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A Report Submitted in Partial Fulfillment of the Requirements for the Degree of:

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[QUALITY MANAGEMENT SYSTEM DEVELOPMENT]

Abstract

With Chiptech's current growth rate and size it has become necessary to develop a Quality Management System to enable repeatability, meet customer demands, and protect Chiptech from staff turnover. ISO 9001 was identified as a base for development, with the imperative that the system identified and developed must deliver value for Chiptech. Several frameworks were investigated, along with journal articles and discussions with industry members in order to determine the aspects that would deliver value, and determine the key success factors. Two factors were identified as critical: employee involvement, and the utilisation of metrics – both of which were leveraged for the project results and recommendations.

The systems developed have already proved they offer benefits, however, in order to maintain performance Chiptech must a) keep evaluating the measured results, b) ensure that quality forms an integral part of the organisational culture and, c) continue the systematic approach of continual improvement.

Acknowledgements

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For assisting with identifying how to deliver the quality obtained data clearly, and in a fashion that is easily readable by all, I would also like to thank Daniel Tredennick.

For all industry members that were willing to take their time off to quickly discuss the implementation, benefits, and successes of their quality management systems I give thanks, and honour their desire not to be identified in this document.

Finally, I would like to thank the course supervisor, Piet Beukman, for the knowledge imparted throughout the year, and Beverley Hall, for her tireless support of myself and the entire class.

Nomenclature

External Customers	Purchasers of the final product
Hygiene	Refer to Dual Factor Theory, section 5.4
Internal Customers	Any person receiving a product at any stage in-house. i.e., the Assembly stage is considered the "customer" of the TH/TEST stage
ISO	When used alone, used to refer to ISO 9001 specifically
Jasper	In-house production software
QC	Quality Control
QMS	Quality Management System
SMT	Surface Mount Technology (a production Stage)
Telecare	Industry of emergency response or social alarms
Telehealth	Industry of remote questionnaires/medical readings
TH/TEST	Through-hole/Test (a production Stage)
TPS	Toyota Production System
TQM	Total Quality Management

Document Revision Log

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0	20 Jan 2013	Carl Hodder	Initial document, for review.
0.1	22 Jan 2013	Carl Hodder	Reviewed by Dave White, changes by Carl Hodder.
1.0	31 Jan 2013	Carl Hodder	Reviewed by Paul Wright, changes by Carl Hodder. Submitted to Piet Beukman for review.
1.1	7 Feb 2013	Carl Hodder	Reviewed by Piet Beukman, changes by Carl Hodder.

Executive Summary

Project Purpose: Implement a QMS that offers value to Chiptech.

At what stage should an organisation develop a QMS? Benefits are obtainable at almost any stage – however Greiner's growth curve indicates that the most desirable position is at (or prior to) the crisis of autonomy, which was identified as Chiptech's current position at the time of launching this project.

Literature indicates that the value of developing a QMS includes (but is not limited to):

- An increase in customer satisfaction
- A decrease in the number of complaints
- A rise in repeat purchasing by the customers

Other notable impacts include:

- Improved traceability
- Reduced wastage and defects
- Increased employee involvement
- Process repeatability – consistently make the same product

An additional and significantly salient aspect given Chiptech's current position was: ***To document procedures, protecting knowledge from staff turnover*.** Chiptech's size meant that significant weight was given to this.

Intrinsically the core benefits of the QMSs investigated are the following:

- To provide discipline
- To contain the basics required for business
- To integrate marketing and customer involvement throughout the organisation

The literature indicates that frameworks such as Total Quality Management (TQM) and frameworks such as the Toyota Production System (TPS) offer valuable concepts in addition to ISO 9001. In comparison to ISO, these frameworks have a tendency to concentrate more on the "soft"/people aspects of management.

Key Success Factors

Those points identified as key success factors (in terms of ensuring that the value-add exists for Chiptech) were identified from both literature and discussions with senior industry members as:

- Company culture
- Employee involvement
- Communication
- Cost (both development and implementation)

A further two critical key success factors have also been identified:

1. ***Employee participation and commitment***

Multiple sources confirmed that both push and pull forces are required for success. Enabling the supporting pull factors (i.e. motivating staff) was crucial to achieving valuable results. Interestingly this conclusion was contrary to one of the principles of ISO - driving quality from the top down only.

This critical success factor launched an investigation in motivational theory, initially covering Maslow's Hierarchy of Needs, through to Herzberg's Dual Factor Theory. In terms of application, Maslow's Hierarchy needs careful consideration when considering overall business operation. Whereas Herzberg's theory introduces the level of granularity required for making singular decisions and analysing specific aspects for improvement/development.

Even through the limited timeframe of this project, communications with staff played a significant role in obtaining the desired outputs. The production staff were asked to actively participate and share their knowledge – they are the experts in Chiptech's product manufacture.

The second critical key success factor was identified as:

2. ***Measurability - Ensuring proper measurements***

Literature indicated that firms who did not monitor their successes were those most likely to fail at implementing a QMS. The inclusion of metrics can help drive culture (i.e. rewarding improvements, employee involvement or enabling innovation), can prove the effect of affirmative action, and ensure that improvement policies retain their effectiveness over extended periods of time.

It was discovered that the guides for TQM were significantly biased towards ensuring results over their ISO 9001 counterparts. During this project, these guiding factors and suggestions were utilised often as they aligned with Chiptech's strategic goals.

Project Outputs:
The project outputs and the process to achieve these have been detailed in section 6. The main outputs identified during the initial planning stage included:

- Document Control
- Quality Manual
- Business Goals and Long Term Planning
- Identifying and Recording Major Processes
- Measuring and Monitoring Processes, and Analysis of Measurements
- Resource Allocation
- Management Guides

Additional deliverables were identified during the project for QC and measurement purposes, including:

- Software applications for generating quality measurement data, to be delivered in a graphical format
    - This develops and drives improvements in quality production, sales, servicing, and parts ordering.
- Sales forecasting overhaul - Introduced the ability to forecast sales on a month-by-month basis, and use this information to feed the part consumption forecasts
- Parts forecasting overhaul - show the forecast of parts consumption in an interactive visual format
- Parts ordering overhaul - Allow parts ordering to be executed from a visual tool, with the orders grouped by supplier(s). This generates orders with the destination details and content completed automatically

Recommendations Outside of Quality Management:
The introduction of formal learning-cycles within the company would deliver additional benefits, including lessons learned development – this is not usually identified within QMS frameworks, but offers many supporting benefits.

TPS (Lean manufacturing) was researched during this project and has been proven to deliver results in industry. However it would not be advisable to juggle this and the QMS implementation - so this would need to be considered only after progress elsewhere has stabilised.

Recommendations Related to Quality Management:
For the purpose of future development and analysis, Chiptech would benefit from the use of the additional tools identified. Coupled with the application of metrics it will be possible to constantly improve not only the current outputs, but future development cycles (through the enabling of double-loop learning).

There are still parts of the system that require further development as the current system is not mature enough to support all of the changes required:

- Further management integration and documentation
- Resource allocation improvements, and success measurements for this
- Continuous improvement culture
- Auditing

A study (in section 4.6) indicated that **auditing shows benefits for organisations with new QMSs**. This is due to the reflection that occurs when identifying compliance to an identified set of criteria, indicating required improvements. With the current level of development it would not be advisable to implement this (other than for QC), as the time would be better spent elsewhere. Once the system is mature enough (management to decide) then auditing will form another QMS development tool.

A QMS is built around the quality of the employees – thus in order to implement and continue the ideal of continual improvement it would be wise to encourage participation in development, including seeking input from all employees. Communication will also allow a certain level of ownership to evolve. Without this the rigidity will stifle any potential for creativity and innovation, and make the job lacklustre which disenchants staff and decreases work efficiency.

Finally**, a QMS is not something that is developed and implemented within a handful of months**, rather it is **a constantly evolving system**. Progression and effort on this behalf needs to continue into the future in order to truly obtain 'value for Chiptech'. With this in mind, it is important that future development of the QMS is considered in the same vein as product development. **Additional developments should be validated to have sufficient value to the customer (Chiptech)** before becoming part of the mandated processes. This should also aid in ensuring that the QMS does not degenerate into a paper bureaucracy, and is instead an integrated system that adds value.

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1 Introduction to Chiptech Ltd

1.1 Chiptech's Business

Chiptech designs and manufactures medical alarms for the elderly. The majority of the business is based around telecare - however, telehealth and remote rehabilitation have been identified as future market trends.

Chiptech currently employees approximately 20 people. This figure has varied recently.

1.2 Company Structure

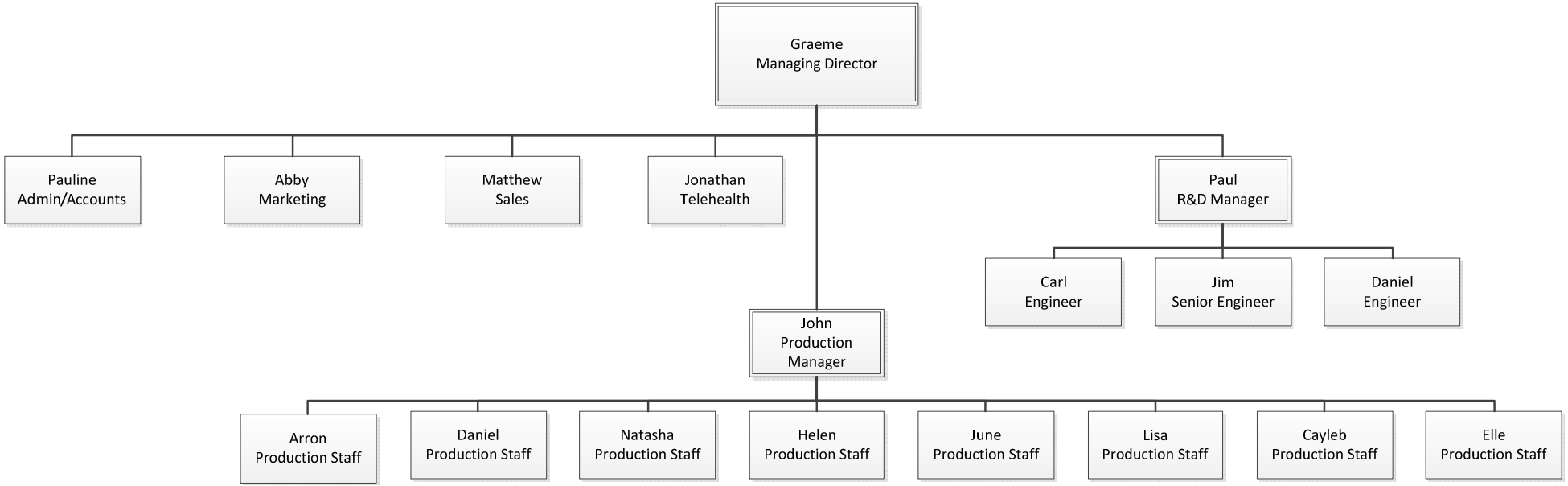

Figure 1: Company functional structure

2 Project Objectives

2.1 Purpose

The purpose of this project is to establish the general policies governing Chiptech's Quality Management System. These policies define management's intention for managing the operation and activities in accordance with a framework suitable for the ISO 9001:2008 standard. These high-level policies represent the company's plans and protocols for achieving quality assurance and customer satisfaction, while any lower level policies identified guide the control and management of conforming and non-conforming product.

After contact with customers, it was identified that ISO 9001 did not offer them significant value. The scope of the project altered accordingly, so rather than following ISO 9001 exactly the goal was to:

Implement a QMS that offers value to Chiptech.

This was still to follow the ISO framework where possible. Justified variations and extensions were deemed acceptable in order to take the knowledge of the experts that created ISO and refine this to help Chiptech grow. Information used throughout this project was leveraged off a number of publications such as books, journal articles and others, as well as discussions with industry members who have previously experienced QMSs.

2.2 Scope

The Scope of Chiptech's Activities are:
The design, manufacture, servicing, and sale of medical alarms, peripherals, and solutions.

The policies developed during this project should apply to all operations and activities at Chiptech Ltd.

- It will be the responsibility of this project to develop departmental definitions, create initial implementations of procedures, and educate staff members on use and maintenance of the system
- It will be the responsibility of management to follow procedures and ensure their use in order to strive for continuous improvement in all activities
- It will be the responsibility of all employees to follow these procedures, and to independently strive for continuous improvement in their positions (through feedback to management)

2.3 Methodology

ISO 9001 is an industry recognised and mature framework. However implementing this by rote does not necessarily deliver value, as all businesses differ.

Thus, a portion of this project was dedicated to researching success factors and the history of ISO 9001, as well as gathering data and background information on other QMSs, including: TQM, TPS, business excellence awards, and ISO 13485.

This information was used to indicate key success factors and gaps within the ISO 9001 framework, with the resultant combination having a significant base in ISO 9001 but alleviating any potential issues. This process also included identifying aspects that are crucial to Chiptech, and those that do not add significant value at this stage in the company's growth cycle.

3 When should an organisation develop a QMS?

In 1977, and updated in the May 1998 Harvard Business Review (1), Larry Greiner (A professor of Management at University of Southern California) proposed a model of business growth. This model indicated that an organisation goes through periods of 'evolution' or normal growth, followed by a 'crisis' where action is required to change the business behaviour in a 'revolutionary' step to sustain this growth.

Ideally, using Greiner's curve below, a quality management system should undergo development prior to the "crisis of autonomy". The results from the development of a QMS will aid in ensuring that the business becomes autonomous, overcoming the indicated crisis.

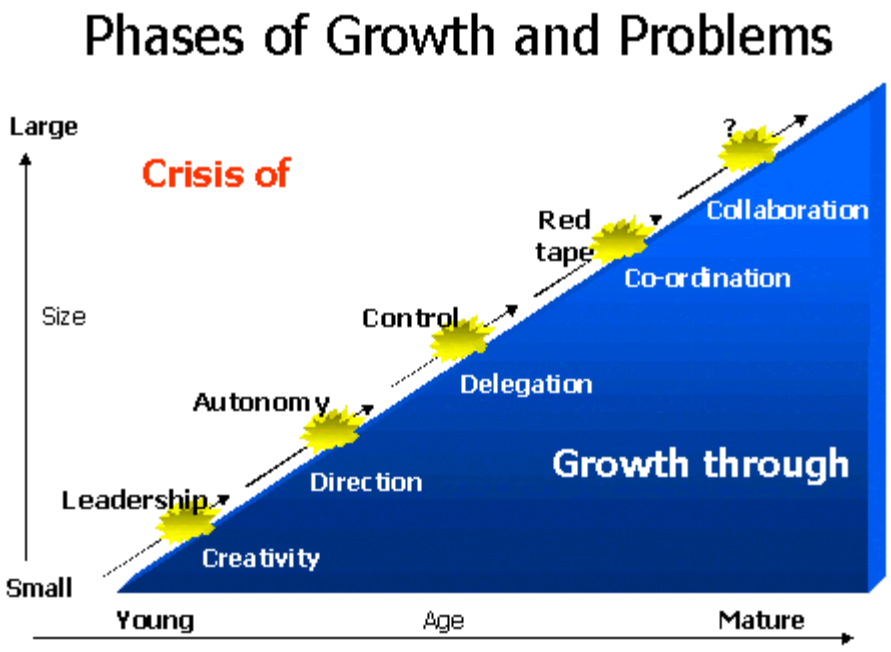

Figure 2: Greiner's growth curve (2)

This is not to state that an organisation will not benefit from a QMS outside of this period, as the complexity of the system developed can be made to match the business. The continual improvement of processes will reflect in superior outputs, as is concluded in section 4. Specific values from implementing a QMS are as follows:

3.1 Value from Implementing a QMS

In order to develop a QMS it is necessary to determine and understand the underlying principles behind the action of developing the QMS, and the desired outputs of such. For this reason, the indicated benefits and their underlying drivers have been identified.

Studies have shown that adoption of the ISO QMS yields measureable results in the form of increased customer satisfaction (3) (4), and this has also been demonstrated by New Zealand industries (5).

Introducing a QMS delivers several other benefits for external customers, as indicated below (6):

- A decrease in the number of complaints
- The rise in repeat purchasing by the customers
- Process repeatability – consistently make the same product

Less commonly discussed, but notable impacts include (7) (8):

- Improved traceability
- Reduced wastage and defects
- Competitive advantage, through
    - Higher levels of employee participation
    - Increased work efficiency
- Operational efficiency

Another concept that was not identified in literature, but is incredibly important for a small enterprise such as Chiptech was: **protecting knowledge from staff turnover.** The mechanism of documenting and updating process means that the QMS protects against the loss of a staff member.

> *It is important to mention that the benefits from successfully implementing a QMS such as ISO 9001 were found to be independent of organisation sector or size (44)*

To summarise, Quality Management Systems offer the following definitive benefits, represented through the idealised business practices generated by expert and experienced people (9):

- They provide discipline
- They contain the basics required for good business practice
- They integrate marketing and customer involvement throughout the organisation
- They ensure that the business has goals, and focuses towards the future

The cost and benefits from implementing a QMS must also be considered as many of these costs are intangible or difficult to measure. These ‘costs’ include the effort of prevention, appraisal, internal failures, and investment in continual improvement; whereas the benefits include customer loyalty, reputation, and lower wastage (direct, and through reduced replacement/repairs).

The meaning of quality has evolved throughout the last century and is a movement which has been refined into several frameworks, including ISO 9001 and Total Quality Management (TQM). As discussed in the following section, ISO offers a fairly rigid framework whereas TQM is more “a philosophy that makes quality values the driving force behind leadership, design, planning, and improvement initiatives. The belief is that for long term financial success, quality is essential” (10).

4 Overview of Quality Management Systems

When undertaking the development of something that is novel to an organisation, it is important to investigate from the perspective of both those who advocate the system, and those who offer criticism. This allows the development of a deeper understanding prior to the costly endeavour of undertaking the task, and minimises risk by identifying and understanding where the complexities and issues are.

4.1 Breakdown of QMS Coverage

By investigating comparison studies for ISO 9001, TQM and the Baldrige Business Excellence award (11) (12), it can be observed that QMSs most often cover the following categories:

Table 1: Overview of three major QMS investigated

Category	Overview
Customer Focus	• Driving the business to meet the ideals of the customers • Customer satisfaction surveys • Involvement of the customer in development
Top Management Leadership	• Upper management need to drive the push for quality, and allow resourcing to fulfil the QMS requirements • Including the QMS strategy as part of the overall business strategy plan • Leadership needs to be encouraged, with the roles and hierarchy within the business clearly defined
Quality Control and Metrics	• QC ensures that quality products are being received by the customer • Extensive measurements ensure that quality is maintained, and that areas of improvement are identified
Management of Quality	• Infrastructure exists to control the execution of tasks within the QMS • Ensure ownership of roles • Ensure that the QMS is being continually improved and maintained
Strategy and Planning	• Need for QMS identified • This needs to be backed with long-term planning and strategic goals • Goals are often specified only for the QMS, however some systems advocate the need to for this to be an aspect of the overall business strategy
Workforce Efficiency	• Ensuring staff members are motivated to adopt the QMS • Includes implementing a feedback path for staff to indicate areas for improvement - both immediate changes, and future considerations
Operations Efficiency	• Identifying and improving inferior processes – thus increasing throughput and efficiency • Some systems also include financial metrics to ensure that value has been added
Supplier Management	• Identifies the need to ensure that suppliers are operating in a manner that supports the business • This covers company satisfaction, quality of goods, accuracy of supplier forecasts, enabling relationships to develop, and trust
Knowledge Management	• Ensure processes exist for business activities • Ensure that a system exists to control any alterations and review all documents
Resourcing	• Ensure that resources are allocated sufficiently to allow business endeavours to be successful • Can contain a significant bias towards human resources, as this aspect is

	identified often as crucial and underdeveloped
Training	• In order for a QMS to be successful it is important to train staff in the use, and train for any alterations and improvements to processes • May include training outside of the QMS in order to develop staff further, introducing new expertise within an organisation

Not all QMS cover these topics to the same degree, or often in the same manner – highlights of each are elaborated in the following sections. For an overview between the three major systems identified in this report (ISO 9001, TQM, and Baldrige Business Excellence), refer to section 4.5.

4.2 ISO 9001

Given ISO 9001 was identified in the project charter, this system was covered fairly exhaustively. This section contains a breakdown of ISO 9001 in terms of its guiding requirements, and the identified goals from an organisations perspective.

David Hoyle's guide indicates that ISO 9001 can be roughly condensed into 7 requirements (13):

Table 2: ISO 9001 requirements

Purpose	Establish the organisation's purpose and the needs/expectations of stakeholders relative to this purpose.
Policy	Define, document, maintain and communicate the overall intentions, principles and values related to quality.
Planning	Establish objectives, measures and targets for fulfilling the organisation's purpose and its policies, assessing risks and developing plans and processes for achieving the objectives that take due account of these risks.
Implementation	Resource, operate, and manage the plans and processes to deliver outputs that achieve the planned results.
Measurement	Monitor, measure and audit processes, the fulfilment of objectives and policies and satisfaction of stakeholders.
Review	Analyse and evaluate the results of measurements, determine performance against objectives, and determine changes needed in policies, objectives, measures, targets and processes for the continuing suitability, adequacy and effectiveness of the system.
Improvement	Undertake action to bring about improvement by better control, better utilisation of resources and better understanding of stakeholder needs. Results might include innovation and learning, and is usually executed through constructive feedback and discussion.

4.2.1 Organisational Level

The guiding goals at an organisational level can be condensed down into five assurance requirements.

1. The organisation shall demonstrate its commitment to the achievement of quality.
2. The organisation shall demonstrate that it has effective policies for creating an environment that will motivate its personnel into satisfying the needs and expectations of its customers and applicable statutory and regulatory requirements.
3. The organisation shall demonstrate that it has effectively translated the needs and expectations of its customers, and applicable statutory/regulatory requirements into measureable and attainable objectives.

4. The organisation shall demonstrate that it has an effective system of interacting processes for enabling the organisation to meet these objectives in the most efficient manner.
5. The organisation shall demonstrate that it is achieving these objectives as measured, that they are being achieved in the best way and that they remain consistent with the needs and expectations of their customers and applicable statutory and regulatory requirements.

4.2.2 Limitations of ISO 9001

A limitation most often proclaimed about ISO 9001 is primarily due to its rigid structure stifling creativity (14) (9), as its strict measures supress healthy discourse. Chiptech must ensure that the QMS implemented does not suffer from this.

In Jack Dearing's (9) opinion, he believes the standard's 'flaws' (specific to ISO 9001) revolve around the extraneous effort required for certain aspects that do not "add value" to an organisation. Two of these are identified below:

- The "root flaw" of ISO: the reliance on **third party** audits. The resources used during this process could be better spent further developing and investing in the quality system. Wasted resources have two impacts: a) the waste itself (financial cost), and b) the good that could have come otherwise (opportunity cost).

- "More than half" of the requirements do not contribute directly to controlling or improving quality. These requirements are an overhead burden, and this detrimentally affects the cost perceived from the implementation of ISO 9001. This balance is not considered given each unique application of the framework.

Chiptech is actively applying the ISO standard, and other QMSs discovered, in an approach that avoids or mitigates these issues.

4.3 Total Quality Management

Total Quality Management (TQM) is another common QMS used within industry. W.G. Lewis et al identified 12 principles that are the most common, and most valuable, during the implementation of TQM (15):

1. Quality data and reporting
2. Customer satisfaction
3. Human resource utilisation and performance
4. Management of process quality
5. Training and education
6. Management commitment
7. Continuous improvement
8. Leadership
9. Strategic quality planning
10. Performance measurement
11. Customer focus
12. Contact with suppliers and professional associates were advocated by many researchers in their studies

These principles indicate that the desired outputs of TQM appear to contain a sub-set that applies to ISO 9001. Studies have indicated that TQM is not contradictory to ISO 9001 but that ISO can be utilised as a baseline for TQM development (16) (17). TQM has a greater emphasis on 'soft' qualities, such as leadership, strategic planning, quality culture, employee involvement/empowerment/satisfaction. These are all of great consequence for ensuring the QMS performs as desired.

4.4 Other Quality Management Systems Investigated

Note: See Appendix A: Other Quality Management Systems Investigated for a more verbose description of each of the following:

4.4.1 ISO 13485:2003 - Medical Devices, Quality Management System s

Given the level of complexity in this standard, above and beyond that of ISO 9001, it was not chosen at this time for consideration. There is little risk in this choice, as:

- These are offset by the benefits from developing a more targeted and valuable QMS
- This standard is not required or identified as such in Chiptech's industry sector
- This can be added to Chiptech's QMS at a later date

4.4.2 Toyota Production System

TPS is not a quality management system, but rather a production framework. It has similar principles and goals, and is often developed in parallel to a QMS in organisations. TPS revolves around 6 principles (18) (19):

- Continuous improvement
- Respect for people
- Long-term thinking
- The right process will produce the right results
- Add value to the organisation through your people, and partners
- Continuously solve the root problem, and this will drive organisational learning

It is worth noting that this last point is also Argyris' Double Loop Learning, identified in section 5.3.

4.4.3 Baldrige Business Excellence

The Baldrige Business Excellence is a United States award given to businesses demonstrating exceptional management practice. This is used to identify exemplary organisations to use as examples for others, and as such the exact implementation of "Quality Management" is not specified - only the outcomes and the presence of a definable system.

This places Business Excellence in a category outside of pure Quality Management as it is not a framework, a standard, nor a tool. However it does provide essence for future development, and a self-critical process for grading a business to determine areas to strive for improvement. It should be noted as the next progression – it delivers a rather heuristic approach to developing an "ideal business".

The available marking schedule can be used as a guide or a benchmark once the base principles of Chiptech's QMS have been implemented and accepted.

4.5 Simple Comparison of QMS Coverage

Using the results from the investigations above, with the addition of two journal articles comparing the QMSs (11) (12), the following table was produced to give a quick overview of the topic coverage.

Table 3: Overview of QMS topic coverage

	ISO 9001	TQM	Baldrige Business Excellence
Infrastructure Documentation			
Quality Policy	X	X	X
Quality Manual (> 30 pages)	X		
Document Control	X	X	X
Auditing Process	X		X
Formal Accreditation	X		
Leadership			
Managing for Quality	X	X	X
Processes for Management	X	X	X
Measured Teamwork and Motivation		X	X
Public Responsibility			X
Information and Analysis			X
Management of data	X	X	X
Benchmarking		X	X
Strategy and Planning			
Processes driven	X	X	X
Performance plans	X	X	X
Long term objectives	X	X	X
Human Resources (HR)			
HR resource plans	X	X	X
Employee involvement	X	X	X
Training	X	X	X
Employee Performance		X	X
Employee well-being		X	X
Management of Quality			
Design quality	X	X	X
Process management	X	X	X
Support management	X	X	X
Supplier quality assessment	X	X	X
Quality Control (QC)	X	X	X
Cost of implementation considered		X	X
Focus on improving efficiency		X	X
Business Results			
Quality Results	X	X	X
Operational Results	X	X	X
Financial metrics		X	X
Customer Focus			
Measured expectation feedback	X	X	X
Customer Involvement in Development		X	X
Relationships developed	X	X	X
Relationships measured	X		X
Reflection on results	X	X	X

4.6 Critical Analysis of Offerings and Conclusions

As identified earlier, offerings other than ISO 9001 are more abstracted and are more heavily concentrated on the "soft" aspects of business such as:

- Employee involvement and empowerment
- Customer involvement
- Company cultures

This is where previous experience has shown the native benefits of a small business lie, especially with regards to communication, involvement and agility. Another possibility for this trend lies within the nature of the ISO standard and its audits – "soft" criteria are considerably more difficult to measure and prove with factual information whereas "hard" factors are usually more systems oriented and measureable. One premise is that "soft" processes are considered too judgemental to include in an official audit process, and are thus excluded from the standard itself.

> *Despite this, studies have shown that auditing has been beneficial for those companies **starting** a quality management system (involving 300 AUS/NZ auditors and 1500 companies (45))*

Although, auditing is not always beneficial - this study indicated that those organisations with a **mature** quality management system did not benefit from audits, suggesting that this acts as a tool to provide feedback on progress during development. This leads to the question of what other qualities are required for success in implementing a QMS, which are discussed below.

4.7 Key Success Factors for QMSs

The success of implementing a QMS depends on several vital organisational factors:

- Culture
- Employee involvement
- Communication
- Cost (both development and on-going costs)

During both the literature investigation and discussions with industry members one common theme was emphasised. This critical success factor was indicated as one of vital importance, if not the most crucial of these factors:

- **Employee participation and commitment**

A quality management system describes the entire system from how the product or service is developed through to design and strategic planning. All organisation members are involved in this during some part of the process, and thus the processes cannot be properly managed without the involvement and understanding of all team members in the organisation.

> *A series of surveys (257 respondents) showed a statistically significant correlation between personal responsibility/buy-in, and success (46).*

The same results above suggest stimulating adherence to the QMS should be fostered through an atmosphere where informal reflection on each other's work is encouraged and employees are

empowered to discuss potential issues. The latter point occurs through implementing a culture that does not persecute mishaps and mistakes, but instead treats them as ways to improve both the individual and the process. Suggestions from others include promoting process ownership (20), and creating distinct and balanced tasks, responsibilities, and ensuring clear authority (21).

A second theme that was identified in studies by both Fowler (22) and Kumar (23) as crucial is:

- **Lack of measurability / Lack of proper measurement**

Results indicated those firms that did not put in place measurements to monitor success, both in the output and fiscally, were those most likely to fail to correctly implement TQM (and this can be correlated with other QMSs as well).

It would appear that developing the correct culture and using measurements to prove performance, celebrate successes, and show improvement (rather than incurring penalties) offers the best approach to ensuring the efficacy of the implemented processes.

4.7.1 QMS Performance Stages for Internal Auditing

As auditing was identified as having potential to ensure development is successful, further literature was investigated. A paper involving the Hong Kong electronics identified four distinct stages of QMS development and performance (24). This information has been included in the 'internal audit' aspect of the QMS, which will be used to ensure that the QMS is conforming to the original intent. These stages and their identifying characteristics are described below:

Table 4: Stages of development identified in Hong Kong electronics industry

Development Stage	Characteristics
Underdeveloped QMS	• Very little leadership • Little infrastructure • Respond passively to customer requirements • Often lose customers • Major QC inspection is final stage only
Framed QMS	• Formal control procedures • Employees not trained • Approach customer requirements in a 'fire-fighting' style • No quality-conscious culture
	Cost efficiency was identified as positive for organisations below this line
Accommodating QMS	• Provide training • Established hierarchy for QC • Actively seeks to develop and improve outputs • Suffers from insufficient management involvement • No strategy for QMS future
Strategic QMS	• Long-term QMS strategy defined • Heavy reliance on measurement and monitoring of quality metrics • Roles and responsibilities clearly defined • QMS is part of business strategy

Applicability to Chiptech

The categories above demonstrate a fairly simple critical-reflective approach to determining what stage the QMS is currently in, and where improvements are required in future. This also adds extra

benefit in highlighting whether Chiptech has implemented the depth required to achieve a positive cost-efficiency, as identified by the research.

It is also interesting to note that the companies recorded in the 'Strategic QMS' phase had the highest number indicating the use of a TQM system (35%, a factor of 2 more than other stages).

4.7.2 QMS Development Steps for Success

Given the similarities between ISO and TQM in both the implementation and execution phase, most information from one can be applied to the other. John Oakland, a renowned author in the Quality industry, gives the following 10 basic steps for ensuring success when implementing TQM (25):

1. Gain commitment to change through the organization and with top management. This is crucial to success.
2. Develop a shared 'mission' or vision of the business. Generate awareness, educate project staff, and change attitude.
3. Define the measurable objectives, which must be agreed by the team, as being the quantifiable indicators of success in terms of the mission.
4. Develop and document the approach to TQM of projects, but be wary of degenerating into a paper bureaucracy.
5. Develop the mission using the identified critical success factors (CSFs), and use these to coerce and move it forward.
6. Breakdown these critical success factors into the key or critical processes and gain/allocate process ownership. Prepare project quality plans for all levels of work.
7. Breakdown the critical success factors into sub-processes, activities and tasks and form improvement teams around these.
8. Monitor and adjust the process alignment (see SPC in Appendix D: Tools Introduced) in response to any difficulties.
9. Promote staff participation and contribution, and initiate motivation programs. Communicate all the activities, progress, and results to the related team members and management.
10. Review quality plans and measure performance.

All of the above processes reinforce statements made from those journals investigated delivering steps and key success factors for the implementation of quality management, whether it be ISO 9001 or TQM. These steps and guides were used in the initial stages of development, and have been included within the QMS documentation for future benefit.

4.8 Research Benefit for Chiptech

The analysis of these QMSs allows Chiptech to determine what aspects are beneficial to the organisation, and how best to ensure that this endeavour is met with success. Other research around supporting systems and QMS criticisms allows Chiptech to determine what their QMS will become in the future – enabling a long term vision for development.

5 Motivational Theory / Employee Psychology

As this was identified as a critical success factor, an investigation into the psychology behind motivation in organisations offers benefits for current and future development. There are numerous articles on this topic, including analysis in the field of practical application. Understanding how employees react to stimulus can aid in ensuring the culture required for business efficacy is maintained.

> *In addition to benefiting work outputs, increases in employee motivation have been indicated as a key factor in ensuring the retention of staff, which saves the business considering the cost of turn-over has been estimated at >25% of the base salary of an employee (49).*

The theories of four notable psychologists are summarised below, in a descending order of abstraction from enterprise.

5.1 Abraham Maslow's Hierarchy of Needs

Maslow described the human needs in a hierarchical fashion – a satisfied need would give rise to the demand for the next level to be satisfied. A lack of satisfaction in a lower factor will shadow the above, given its larger importance to the individual. Maslow's Hierarchy of Needs is given below:

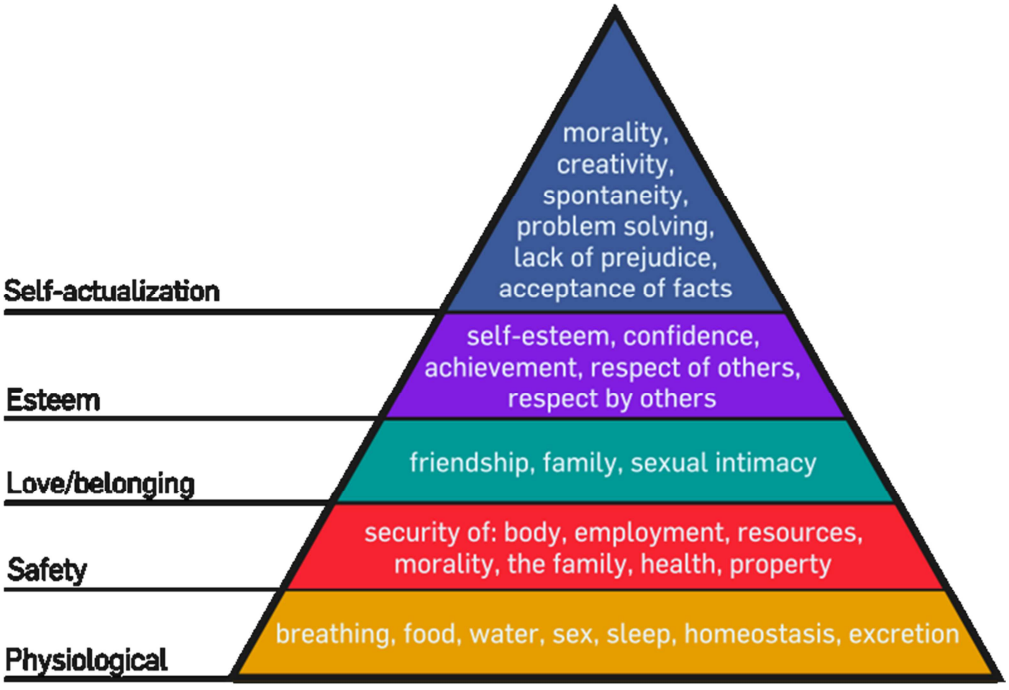

Figure 3: Maslow's Hierarchy of Needs (26)

This model is applicable when considering either the entire organisation or a single role, allowing management to judge whether the role(s) are meeting the needs of staff.

5.2 Douglas McGregor: Theory X and Theory Y (27)

Douglas McGregor proposed two different management styles used to motivate staff:

Theory X:
The theory assumes the employee is inherently lazy, will avoid work if possible, and that there is an instinctive dislike for work. As a result, management needs to closely supervise and control the employee's environment. Theory X requires a basis of threat and coercion to obtain work compliance. McGregor indicates that one major flaw of this approach is that it suffers from dis-economies of scale – the larger the number of employees allocated to a manager the worse the results.

Theory Y:
In theory Y, management assumes the employee is ambitious, self-motivated, and that the employee exercises self-control – work is as natural as play. McGregor indicates that Theory Y managers are more likely to develop a climate of trust that is required for more complex tasks.

Combining the two:
McGregor indicated that one method does not always offer an advantage over the other; rather differing applications require different methods or mixtures of these two extremes. Theory X relates more closely to creating a tightly controlled environment and requires significant management input, whereas Theory Y resembles fulfilling the higher levels of Maslow's Hierarchy of Needs (esteem and self-actualisation). Esteem and self-actualisation are often preferred when a more creative and problem-solving environment is desired, and this the management style suits supporting a valuable QMS.

5.3 Chris Argyris – Action Science

The core of Argyris' model is similar to Theory Y, in that mature workers desire additional responsibilities, variety, and participation. Action Science was developed studying behavioural patterns in difficult situations (28), and proposes two separate methods of learning. The first example is the most common; however management should strive to enable the second:

Single loop: where changes are made by observing the difference between expected and obtained outcomes.

Double loop: where the individuals involved question the entire system, including the values, assumptions and policies that led to the actions. Double loop learning is essentially discovering and affecting how single-loop learning occurs.

Argyris encourages developing a more critical-reflective orientation for employees in an organisation in order to allow members to consciously reflect and develop in a supportive and stimulating environment (29). The resultant system will be one that ensures that workers are involved in developing their skills and the skills of others in a way that ensures repeat errors do not reoccur, and that future errors are avoided.

5.4 Frederick Herzberg (Dual Factor Theory) (30)

Herzberg's Dual Factor Theory proposed that people are influenced by two sets of factors:

Table 5: Frederick Herzberg's Results

Motivation Factors	Hygiene Factors
Sense of achievement	Company policy and administration
Recognition	Supervision
The work itself	Relationships with co-workers
Responsibility	Pay and benefits
Advancement and growth	
Pay and benefits	

This theory was developed following research carried out on 200 engineers (31), and the results have a distinct value for business. The results displayed in Table 5 are ordered in descending order of priority, which indicates that pay and benefits as one of the lowest factors influencing job satisfaction.

The trial results indicated that of the two approaches (motivation/job enrichment vs. hygiene) the act of motivation offered a larger benefit when targeting increased employee efficiency. Motivation factors were shown to have a much longer term effect on the employee's attitudes over their hygiene counterparts, and that the demand for these does not occur as often as that for hygiene.

> *Does motivation work? A study on construction workers showed an astonishing increase of 80% in work efficiency with the introduction of motivation and hygiene factors within the workplace (50)*

The result above underlines the efficacy of ensuring that both motivation and hygiene factors are included in business consideration, and the QMS policies developed should reflect this.

Herzberg's concluding notes suggest that job enrichment is not a once-off but rather a continual management function, bringing the job level up to be commensurate with the skill of the employee. The result is that those employees who have more ability will win promotion to higher level jobs.

5.5 Conclusions for QMS Development

In terms of the applicability to Chiptech, these will deliver benefit if applied correctly.

- **Maslow's Hierarchy of Needs:** This should be used to determine whether Chiptech is providing sufficient support and fulfilling roles, ensuring the lower levels of this hierarchy are met –so that the full benefit of supporting the following management style is realised:

- **Theory Y Management:** Chiptech should strive to maintain this open style of management in order to support staff members to develop a creative and innovative problem-solving environment. This will also enable the third point:

- **Motivate employees:** Indication was given that coupled with a 'Theory Y' management style, distinct increases in work efficiency and employee satisfaction (important for a QMS) can be achieved. This will enable an active, creative, and supportive environment. This will complement and assist the drive for a quality-centric culture

- **Double-Loop Learning:** Finally, Chiptech should encourage time and resource allocation for double-loop learning. A QMS system is in itself based around the application of this– the continual improvement culture that is centric to all the QMSs analysed requires altering the process that allowed the fault to occur, not just the fault itself. This reflective mentality should be developed throughout the organisation.

6 Project Implementation and Results

6.1 State Prior to Project

In order to develop Chiptech's QMS the current position of the company must first be understood. The follow section covers the initial state of the documentation, a summary of a departmental meeting indicating desired changes, and finally covers a brief on the production management software that is discussed later within the report results.

6.1.1 Initial Documentation and Processes

Given the size of the company there has historically been a lesser need for documentation. This was due to the direct involvement of employees across multiple departments, allowing direct influence in all departments. Unfortunately as the business grows this is no longer the case – employees are finding that their time is taken up in repetitive support roles, so the need to formally share information has been identified.

Documentation existed previously around some manufacturing processes. However, most of this was for a product range that has been superseded. With the increase in sales and growing demand for the newer products, it is essential that proper procedures are created and documented in order to ensure that quality is upheld.

6.1.2 Departmental Meeting

The engineering department held a meeting after losing two staff members in order to determine:

1. Current issues, internal and external to the department
2. Desired future roles
3. Role reallocations

The issues identified during this meeting have a significant correlation with the lack of quality management systems in place, with the minutes indicating:

- Misunderstandings with specifications
- Issues with resource allocation
- Too many distractions from required production maintenance/support
- A lack of necessary testing and poor documentation

The issue of resource allocation of staff is potentially more influential than first expected (see below), and this indicates that a solution is required in the long term.

> *Michigan State University demonstrated that even momentary interruptions of three seconds can double the rate of errors when concentration is required (47)*

The correction of the final two bullet points from the meeting is expected to deliver benefits in culture, and aid in ensuring that the first step is taken towards ensuring the correct (human) resources are allocated within the business (details in section 6.9.1).

6.1.3 The Production Management System (Jasper)

As part of the project resulted in significant changes and additions to this software, an overview is given below. The current production system controls and tracks the processing of all products, and includes features such as:

- Stock control and forecasts
- Production management (for all product)
- Servicing/warranty control
- Sales
- Interfaces for running production machinery

This system already has the necessary framework to support the requirement for control of non-conforming product that ISO 9001 identifies, and this has been noted in the quality manual (see Appendix B: Document List for summary), and below:

- Production is tracked on an item-by-item basis for barcoded products, if a 'stage' has not passed due to failure, then it cannot be processed and distributed to a customer
- For non-barcoded products this must be included in the design of the device, often using the internal programming of each device to ensure that it is not possible to undergo the final test stages required for shipping. Alignment of the design process with the quality manual will ensure that this consideration is maintained in future

6.2 Project Goals

In order to develop and execute the project plan the objectives identified were broken down into 7 categories, and the project results are included under these headings:

1. Document Control
2. Quality Manual
3. Business Goals and Long Term Planning (Confidential and excluded from report)
4. Major Processes
5. Measuring and Monitoring Processes, and Analysis of Measurements
6. Resource Allocation
7. Management Guides

The process undergone and the results obtained for each of these categories are given below:

6.3 Document Control

The importance of document control is two-fold. First, having identified ISO accreditation as a possibility for the future, it is a requirement that change-tracking and release procedures exist for accreditation. Secondly, if all these changes are recorded it is beneficial for anyone attempting to control/maintain this documentation. This also has the advantageous side effect of adding the perception of importance to any alterations to ensure this process is not treated as trivial.

Given the potential mess of paperwork, a software solution was declared necessary. To this extent, we leveraged the already existing software used by the engineering department – Subversion (SVN). This allows usage control, tracking of line-by-line changes, and allows updates to deploy automatically to multiple locations.

With regards to versioning/change tracking, the built-in log becomes a great boon. This enables exact changes to be determined along with the reasoning behind each. This can be viewed at the level of a single file, sub-folder or the entire QMS allowing information on development progress to be easily obtained.

As paper copies are a necessity of life, a master document list exists in the electronic copy – this contains a list of all QMS documents (useful when looking for relevant documentation), their versions (useful for comparing paper copies), stakeholders, and the **location of deployment**. This is essential as currently out dated information exists in the production department. Previously the original documents have been altered without anyone knowing the existence of one or more paper versions.

6.4 Major Processes

These are quite simply derived from identifying any procedures required to continue 'business-as-usual' and especially those tasks where the knowledge of operation has a single point of failure

Initially, the processes identified as essential to operations included:

- Processes for manufacturing
    - Operating Jasper (Production management system)
    - Operating SMT line
    - Processes for TH/TEST and Assembly
    - Other manufacturing instructions (on-going)
- Product realisation guide
- Quality Control procedures
- Non-conforming product procedures

The project scope did not allow time for writing the vast number of documents required, however, being gainfully employed at Chiptech will allow this endeavour to continue. For a list of current documents that were developed during the project, please see Appendix B: Document List.

6.5 Measuring and Monitoring Process

6.5.1 Software Overview

After starting the project it became apparent that proof of the system's value would be required before momentum could be gained with staff and management. Due to Chiptech's unique way of managing production and sales, a custom tool for obtaining and structuring vital production metrics was required.

Thus, there was a need to include the development of a software application for obtaining these metrics in the project scope. The metrics identified included:

Conforming product:

- Stage Throughput
- TH/TEST and Assembly stages to include pass rates
- Wastage for each stage

Non-conforming product:

In-house:

- Wastage (percentage and total)
- Visual breakdown of failure rates by test

Servicing:

- Failure rates (total, by manufactured quantity, and by date)
- Faults by failure mode

Supply

- Part shortages (Run-outs)
- Change in lead-times

Sales

- Metric of products shipped vs. expected shipping date (I.e. are we meeting promises).

The language chosen to develop this application was C#, selected over others for the following reasons:

- Competency in-house (myself and others)
- Maturity of development suite
- Native support for SQL databases (Linq-to-SQL)
- Ability for rapid application development
- Modularity and expand-ability for future use and development

Some metrics required modification to Jasper in order to obtain the data, and these were executed – however this data does not yet offer a valid benchmark as insufficient history exists. In future the correct data can assist with improvements to both current procedures and new designs.

The main benefits of this software are: to observe previous characteristics, and to use these to set obtainable goals to strive for. Some of the metrics (i.e. the non-conforming products data) offer distinct benefits in enabling the observation of potential issues, allowing a more rapid response than what was previously available. It recommended that these metrics are kept simple, monitored readily, and developed further for areas that Chiptech wishes to improve.

6.5.2 Measurements, Analysis, and Results

The action of creating the metrics analysis software revealed the truth behind the old adage “what gets measured gets monitored”, and the inverse of this statement. The results currently have a large and unaccounted-for variance. Despite this, there exist visible trends and a depth of information that can be obtained from these results. This helped determine the direction forward, and aided with the formulation of baseline targets.

The quality policy identified four categories that required immediate metrics, and results for these are given in the sections below:

- Shipping date accuracy
- Sales forecasting accuracy
- Warranty return percentage
- Parts shortage count

Other metrics identified during the software development process were outside of the current quality policy iteration but will be added later during review.

6.5.2.1 Shipping Date Accuracy

The quality policy specifies a 10% missed shipping date target – measured from the date that was indicated to the customer that the item will be shipped.

Previously Chiptech had averaged at approximately 38% of targets missed; although there has been a trend downwards over the last three months - so there has been progress. Note, the most recent data point (below) at 100% is an outlier due to order system not accounting for the Christmas break.

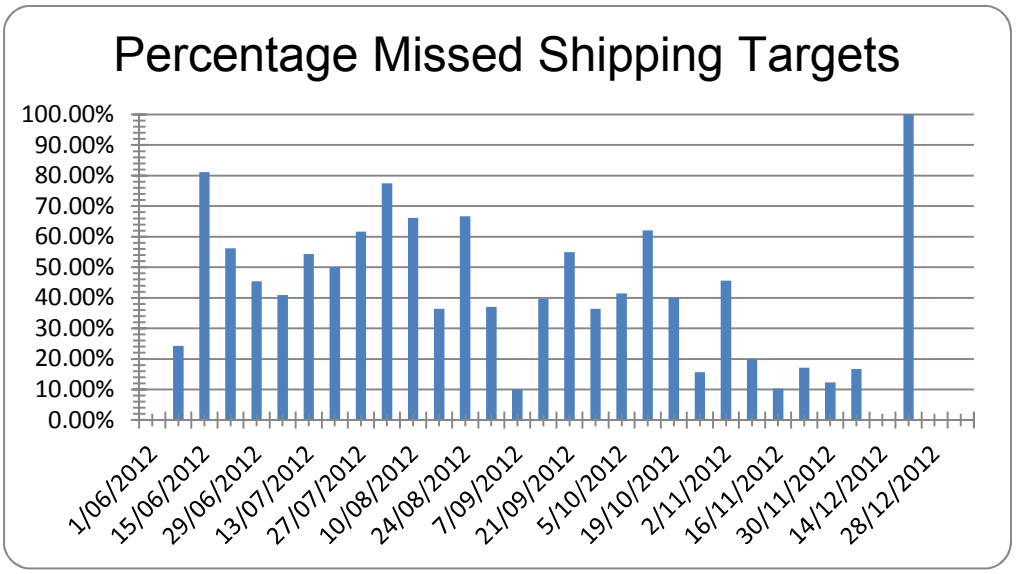

Figure 4: Shipping success rate from June to end-of-year

The weekly sales figures are generated by product, and the results also indicate or can be used to determine the following:

- No distinct cyclic behaviour to orders – data appears fairly random
- Peak monthly and weekly demand – good for determining work-in-progress levels required to meet these periods
- A rough indication on peak possible throughput for a product

6.5.2.2 Production Issue Rates, and Servicing Return Rates

Servicing Return Rates:

Servicing metrics for warranty repairs were generated grouped by manufacture date and as a total figure. For the total units manufactured the number of returns is less than the identified 2% (actual figure omitted due to confidentiality). The manufacture date grouping shows that returns have fluctuated in the past, and there are some patterns that appear to match records from prior issues – thus validating the results and proving the long-term effects of these actions.

Production Issue Rates:
Due to a push earlier in the year to store information from the automated test-jigs in a database, it was possible to obtain metrics for testing and assembly faults for the major products (ERICA, PRU52, Pearl869 and Pearl916).

These results had an initial failure rate higher than expected for some products, indicating an improvement could be made to benefit throughput or correct a reoccurring problem.

Wastage was:

- PRU52 0.38%
- Peal 916 11%
- Pearl 869 8.4%
- ERICA 0.55%

The wastage overall for ERICA and PRU is meeting the target of <1% (identified during this project). The unusually high numbers for both Pearl ranges was due to consumption for testing by the engineering department, and a test having a large type I error.

> *Both figures are now down to 0% and 0.43% respectively over the 12th December 2012 - 13th January 2013 period (with sample size of ~400 units ea.)*

The information obtained from the database also:

- Proved the affirmative action of two investigations prior to this tool
- Launched an investigation on day one after indicating (determined later as) a single component failure from a faulty manufacturing batch
    - This fault had been present since mid-December, but affected units were only placed aside.
- On the same day, indicated the presence of a reoccurring issue
    - Luckily, this was the remainder of a batch, and the issue (minimal, no risks due to testing) had been already corrected

This shows the benefits of monitoring the pass-rates of not only the stage itself, but any patterns occurring within the breakdown of the test results. (See Appendix C: Initial Metric Results for an example on how this data is represented).

6.5.3 Parts Ordering, Part Forecasts, and Sales Forecasting

The quality policy (see Appendix B: Document List) specified a target of “No shortages in production due to lack of parts”. It was identified during this project (from experience, and investigation) that a deficit in the current parts ordering and consumption system within Jasper existed. Due to the similarities with the quality metrics software developed earlier, it was decided that a prototype should be created to test an alternative approach. These core issues were identified as:

1. Lack of sales forecasting ability
2. Complex part forecasting tools
3. Issues with entering parts orders, with no export option

Sales Forecasting:

The information for this item was already being dealt with by Chiptech's sales team, however Jasper does not allow anything more detailed than an average monthly consumption, and the sales pattern do not match this. Thus, the database needed to be altered accordingly in order to support a monthly based sales figure for products.

These sales forecasts are used to drive inventory and parts ordering, so the software was written to be capable of using this information, as well as give a reflection on the accuracy of the forecasts.

Parts Forecasting:

The parts forecasting currently outputs a printed document in the form of:

- Overdue parts
- Parts that need ordering within the week
- Parts that need ordering to maintain a two week buffer
- Parts that need ordering to maintain one month buffer

This report is complex, repetitive (as parts often match multiple categories), does not indicate if there is a "gap" between order arrival dates larger than the order, and can grow to 20-40 pages, allowing for human error. This system required an overhaul in order for the mentioned quality policy goal to be achievable.

The choice of a graphical representation for parts consumption was deemed an intuitive approach to displaying the data, and research confirms this decision:

> *Research shows that visual data comprehension is greater than that of its raw text counterpart – even amongst professionals (51)*

The result was a time-based output based on consumption, visually similar to a horizontal bar-chart, an example of the application is given below:

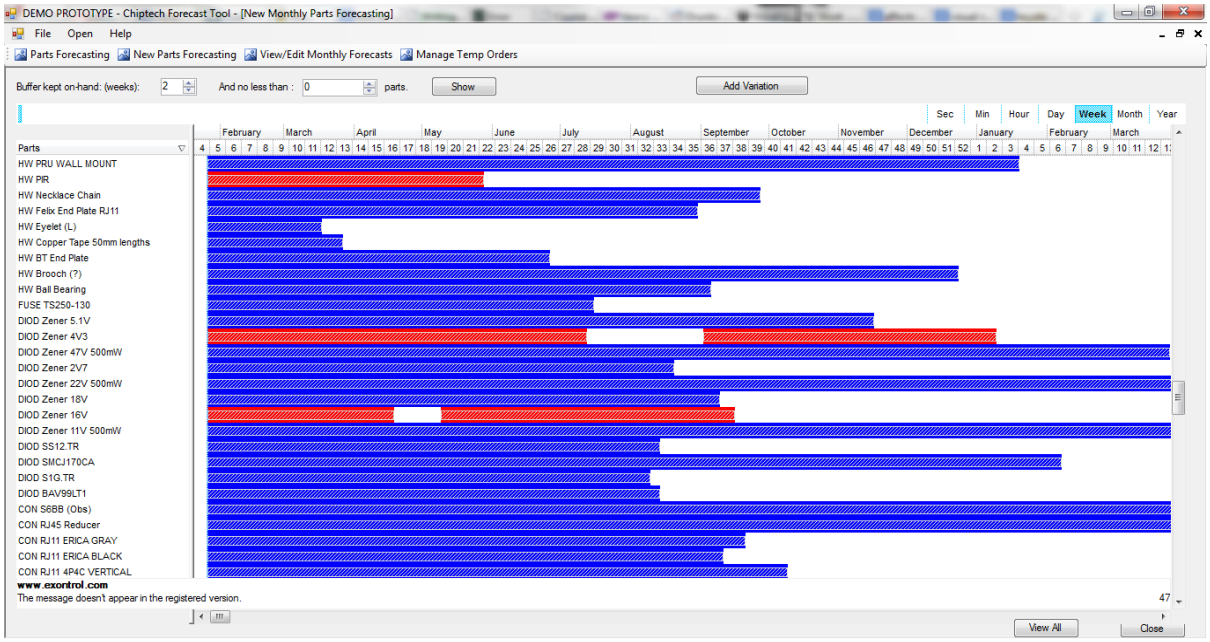

Figure 5: New part forecast application

Parts Ordering:
The third and final software development involved the ability to:

- Create parts orders by supplier
- Copy to clipboard, or create and partially fill an email
    - During this task, simultaneously enter these parts orders into system
- Confirm orders when supplier confirms receipt of order

This will substantially simplify and shorten the time required to order parts, and also centralises and standardises how we order parts to: a) ensure that mistakes are not made, and b) allow for a system that other employees can operate in case of any unforeseen circumstances.

6.6 Resource Allocation

The category of resources covers everything required to meet a projects deliverables (i.e. materials, software and hardware) however the largest and most influential of these are human resources.

A specification of the desirables for this has been created as part of this project; however circumstances have rendered this task unobtainable within the duration given (loss of three staff members, shift of priorities), and it has been identified as a longer-term goal. Despite these issues, resource allocation is occurring in terms of human resources:

- Production is allocated using a work-block allocation system (weekly)
- Engineering is experimenting with using Microsoft OneNote to indicate allocation, as well as deliver feedback on progress

It is recommended that One Note (or an extension of this) be used in the future to communicate resources, as it allows multiple simultaneous users and is easily accessible.

6.7 Management Guides

Initially this was to be a singular guide based around the product realisation guide, but initial progress identified the need to stretch this task. These new documents include the introduction of new tools and frameworks for departments, including quality management tools and risk analysis. These tools included: (see Appendix D: Tools Introduced)

- PESTLE
- Porter's Five Forces
- Cause and effect analysis (Ishikawa diagram)
- Guides for measurement/metrics selection
- Statistical process control framework
- Failure Mode Effect (and Criticality) Analysis
- Observe-Plan-Do-Check-Act guidelines

The Observe-Plan-Do-Check-Act guideline was used during an investigation (launched from information obtained with the quality metric software tool) and its use demonstrated a succinct guide for ensuring that the right possibilities were considered. For the duration of the investigation, this enabled the inspector's lines of logic to be identified and recorded, and also allowed for easy recall when communicating with others (i.e. brainstorming for further ideas). This process has since been pushed to the engineering team for use.

6.8 Other Project Outputs

The list below gives an indication of other duties performed during this project, with regards to my role as QMS developer. These involved encouragement, suggestions and support, and a lead-by-example approach within the business.

Driving Culture Change

This key success factor was identified early within the project and I have taken steps in order to encourage the integration of quality (QC and quality management) within the organisation. These steps included:

- Meetings with production staff members
  - To demonstrate process, and train
  - To get feedback on improvements (to the process under review, as well as other aspects of the organisation)
- Meetings with management
  - Discuss how to drive improvements
  - Discuss quality targets and how to achieve them (i.e. resourcing)
- Give advice for human resource allocation methods and software
- Encouraging general conversations and banter (with permission from management) to keep morale positive and encourage general communication
- Encouraging inspection of each other's work as an un-official procedure
- Facilitate and promote discussion between departments when issues such as specifications and product options/ideas arise
- Drive discussions to clarify specifications and obtain feedback of product and performance from customers – through defined channels (Sales team)

6.9 Conclusions for Small Business

6.9.1 Resource allocation

For a business lacking a diverse range of employees it is desirable to go above and beyond the recommendations that ISO 9001 has describing resource allocation. This meant considering not only the correct allocation of resources to a project, but also that the correct resources are supplied from the right people.

It is beneficial to consider how tasks are allocated, to the extent of considering the necessity of employing another to take over those short-term activities that are allocated to the many (as was identified in Chiptech's meeting, section 6.1.2). This will ensure that the team is capable of concentrating on the tasks at hand.

It is in the nature of a small business to have employees who are proverbial "jack-of-all-trades". This has its disadvantages as the constant switching between tasks suffers from inefficiencies:

> *As was demonstrated by the Ohio State University, subjects that were required to multitask saw a loss of work efficiency of >20% (48)*

This was also identified during the meeting in section 6.1.2 and has been identified as a long-term goal for improvement. One result of this was a resource optimisation involving the development of a new role within the business to reallocate tasks that would otherwise consistently interrupt team members.

Ideally the resultant system should allow some measurement for success, but employee feedback alone would be considered sufficient here.

6.9.2 The Importance of Culture

Culture was identified as a key success factor in section 4.7, and it is important to make sure communication is clear and concise. Chiptech's culture already has a distinct personal aspect due to its size and promoted activities, and it is important that this is not sabotaged. Some benefits of this include:

- Willingness to bring to attention issues
- Willingness to assist and help others
- A personal approach that promotes interaction, which in turn promotes the cross-pollination of ideas and aids innovation and improvement
- Aids in keeping the business functional, and agile

To keep the benefits from this culture we promote discussion, allow (and encourage) playful banter, and organise occasional activities such as lunches, after-work drinks etc. While the above may seem off-topic, it is related to quality management through the results obtained.

Thus, when putting processes and systems in place it helps to make it clear why these have been developed, and that in no way will these be used to punish or blame.

> *Clear communication maintains the lower aspects of Maslow's hierarchy, and is a quick and easy "sanitary" action that maintains employee satisfaction*

This also justifies why a QMS should never be used as a blame system – it does not align with the psychology methods described previously. Instead, targets and metrics should be used to promote self-worth and used for congratulating improvements.

In order to develop a culture of continual improvement at Chiptech, the organisation is encouraging the steps below – and these are recommended for any organisation developing quality management:

- Say "yes" to helping someone – this means do not write issues and actions that are tedious off as "that's the way it is" or "that issue has always existed"
- Meet with production staff – they will spot when some issue is occurring more or less frequently (this can also be good feedback for improvement success)
- Encourage ideas – if staff members mention that something could be better/easier/different or that an action is overly complicated then this can be beneficial information both now and for future product development

The benefits of the final bullet-point have already been demonstrated prior to this project, with staff feedback being obtained for the most recent product. This resulted in a unit being developed that is much simpler to manufacture and costs less in labour to do so, increasing throughput and offering measureable value for Chiptech.

7 Considerations

7.1 Ethical considerations

The obvious item with the most potential for misuse is to target/punish individuals using the results obtained. This potential was identified in prior research, as well as through discussion with industry members. Having been identified and actively included in the quality documentation, this scenario should not occur at Chiptech – the culture Chiptech promotes would also not allow this to occur.

Ethical issues arise around notifying customers about any detected quality failures that may have propagated through to the customer, and this element should be considered on **a case-by-case basis using risk and failure-mode analysis tools.** The results can be used to determine the appropriate level of action in order to protect Chiptech's customers and stakeholders. This process may include the identified stakeholders at any stage if it is deemed necessary.

7.2 Continued Execution: Notes

- **Continual Improvement:** Quality management and quality control both require constant improvement, and it is penultimate that this task is maintained to benefit Chiptech.

- **Measurements:** It is important that measurements are undertaken regularly and acted upon. This ensures that results are repeatable, and that continual improvements can be made to processes. The software created to do this has been scheduled to be run on a weekly basis just prior to the weekly meeting, allowing for a reflection on results to be communicated to the business as a whole.

- **Employee Involvement:** Encouraging buy-in for tasks is incredibly important, and without this it becomes easy to be hindered from further progress. ISO 9001 indicates that changes should be driven from the top (Section 5 of standard (32)), however literature and experience so far shows a system that includes both push and pull forces is required for success.

- **Ownership and Strategy:** Section 8 includes recommendations for future QMS development, and I have been given responsibility for the development of these (on top of QMS maintenance) within Chiptech. Paul, Graeme and Pauline will form the steering committee to maintain and control the strategic drive of this project, and ensure alignment with the organisation's long term goals.

- **Resourcing for QMS:** Having been empowered to maintain this system, it is a requirement that proposals for necessary time allocation are indicated to management. The effects of this system and the benefits shall be executed as a business-case, using measured

performance (i.e. throughput improvement, non-conforming product rates, and customer satisfaction) and indicated intangible values to determine future allocation of resources.

- **Auditing:** To develop the QMS to the extent that it adds value to Chiptech we require an internal process for reflection and section 4.7.2 has outlined some characteristics that Chiptech should strive for with their QMS. In the future it would be wise to develop a custom checklist in order to ensure that the results of our input are complying with what was intended, and use this result to maintain the direction identified by the steering committee.

8 Project Closure, Future Recommendations

To date, a significant amount of the base documentation has been written, and some aspects of the overall QMS have been deployed into the working environment. The most successful and immediate are the metrics deployment, and the improvements for forecasting.

It has become strikingly apparent that in order to achieve success, it needs to be measured. During this project, progress was occasionally stymied due to a lack of evidence, or a lack of a deciding factor. To this extent there has been some documentation developed around the selection criteria for developing new metrics. Systems such as Jasper should be developed (or purchased) with measurement in the forefront of future considerations.

Future development and analysis will show benefits from the uptake of additional tools, and with the addition of metrics the results will be indicative as to whether the overall quality at Chiptech has improved in the next development cycle (in addition to the current outputs). I have high hopes for this result in the future.

There are some tasks remaining in order to further develop the QMS. Of these, the first two items have been identified for the next step in development:

- Further management integration and documentation
- Resource allocation improvements, and success measurements for this
- Continuous improvement culture
- Auditing (internal, not formal ISO 9001 accreditation)

A quality system is not something that is developed and implemented in its entirety within a few months, so progression and effort on behalf of this needs to continue into the future. I would personally recommend that the QMS be treated exactly like product development – i.e. aspects and improvements should not be limited to the scope of what industry has labelled “quality management” – allow for agility and innovation with the system itself. Additional processes that will be developed in the future should also be validated to have sufficient benefit for the customer (Chiptech) before becoming part of the mandated processes.

It would not yet be recommended to implement an audit process for QMS aspects other than QC, given the current state of development this serves no purpose. Once the system has reached an arbitrary level of maturity (management can decide upon this later) then auditing would deliver benefits, as indicated in section 4.7 and recommended earlier.

With regards to ensuring the culture and involvement of employees in the future, it is recommended to not treat the QMS itself and those processes within as immutable. Rather it would be beneficial to encourage improvement. Staff members can be included by explaining why certain aspects exist and encouraging communication. Without doing this the rigidity will stifle any potential for creativity and innovation, making the job lacklustre which disenchants staff from introducing their input. To this end the founding quality statement makes mention of feedback and inclusion, and drives a cultural acceptance of this.

8.1 Factors outside of the QMS

More attention needs to be given to the learning cycles within the organisation. This includes project and QC/operations "learnings", debriefings, discussions, etc. There is tangible value in utilising these processes within the organisation, and resources need to be allocated in order to achieve desirable results.

> *It is important that employee motivation and organisational hygiene factors be considered, not only as the effects of these have been identified as critical for QMS success, but also as these results align with the business goals for Chiptech.*

In the longer term (i.e. once the QMS system has stabilised) it would be beneficial for Chiptech to consider venturing towards developing aspects of the Toyota Production system (Lean Manufacturing). TPS was researched during this project and has been proven to deliver results in industry. However it would not be advisable to juggle this and the QMS implementation - so this would need to be considered only after progress elsewhere has stabilised.

9 Summary of Personal Value – After Action Review

9.1 What were the intended results?

The project was proposed in order to develop the necessary processes required for initiating a QMS at Chiptech. This system was to be based on ISO 9001 with variations to ensure that the result delivers maximum value to Chiptech and their customers. A breakdown of the goals is given in section 6.2.

9.2 What were the actual results?

Through the duration of the project, the development of these processes required additional work in order to develop the required supporting information. This came in the form of software for metrics, further documentation for supporting processes, and the need to maintain clear communication of the objectives throughout.

Benefits were obtainable almost immediately through the application of quality metrics, and these results are already starting to drive the desired company position identified in the quality policy.

In terms of outputs, the results included:

- Base documents for starting QMS
- Framework around document control
- Initial guides and processes

- Quality metrics, and quality metric software
- Staff training on QC, and introductions for new tools
- Future goals, and future development objectives

9.3 What caused these results / what was learned?

Planning and Risk: Both the project results and I would have benefitted through a more thorough planning stage. In the future, more time will be spent truly understanding the scope and risks before developing a comprehensive plan – otherwise the same event will occur, and the project will go over time and suffer project creep. To put this in context of the project, this development process would not have met the quality policy goal of <10% feature creep. Despite this the process undergone allowed these gaps to be identified early, and allowed valuable developments to come of this. Ensuring that the initial research stage is executed first (i.e. not a mixed approach) does offer value and a margin of flexibility.

Delegation: During the documentation aspect, it became apparent that it was onerously time consuming to achieve the level of detail required without utilising others for development and review. Despite requiring another's time, it reduced the overall man-hours required to a more acceptable level, displaying the benefits from delegation of work.

Buy-in: Lack of enthusiasm or buy-in absolutely destroyed certain aspects of the implementation process. However this does give a clear indication on where value is not perceived. In terms of identifying the key success factor of this assignment as "…of value to Chiptech" I allowed progress to occur around these hurdles (unless critical, or distinctly valuable) and the success/improvement experienced from these other tasks is expected to be leveraged to obtain future buy-in for those tasks that were delayed (assuming that these pass a review for 'value to Chiptech'). This approach was successful in terms of work efficiency, and if any future work allows this it this will be considered.

Effects of Measurement: Having targeted a portion of Chiptech's production processes with measurements it has become very clear that in order to guarantee the repeatability of a process it has to be measured. Without having actual recorded data, it is easy to introduce variation or drift – as was observed in the results obtained. Personally, in future, if it is likely that my project outputs will need to be repeatable then these will be developed with a method of achieving this in mind.

Research and Flexibility: The benefits and breadth that the QMS covers are as far-reaching as one allows them to be, extending much further than literature initially suggests. For this reason, when undertaking a large project ensure that sufficient time is allocated to researching what has been done already. Ultimately, this aspect of integrating the QMS with other business processes instead of treating it as a separate entity has delivered significant benefits in flexibility during the implementation stage, and is expected to aid ensuring the longevity of the system.

9.4 What was learned outside of the project?

Theory Y and Motivation: From experience it is fairly obvious that small businesses are acutely biased towards the "Theory Y" management methodology, and these can begin to break down if the size grows without a proportionate increase in supporting management and direction. I observed that freedom becomes chaotic at a certain level. Despite this it is important to maintain this management methodology, as it delivers significant benefits in terms of employee motivation, work

efficacy, and creativity. However the management structure and resource availability needs to be considered in-depth when an organisation grows significantly, as leadership is extremely important for business.

Double Loop Learning: After studying motivation theory and reflecting on prior experience, it became apparent that in an emergency or rushed situation only single-loop learning occurs – the problem is fixed, but the system that enabled the problem to occur is not considered or adapted. Other than those processes adopted into the QMS, one simple process were encountered that counteracts this, as below:

Debriefing: The end-of-project debriefs and (short, weekly) R&D meetings were beneficial for allowing discussion and analysis in more depth. Personally, the value from these meetings is considered more intangible as usually no direct/instant benefits are obtained. These meetings have in the past allowed for the cross-pollination of ideas, sparking new valuable concepts within the company. These results alone show the value behind a controlled meeting targeted towards creativity and sharing knowledge - and any other processes of this type should deliver similar.

> *If you want to ensure shorter meetings, perform them standing up. This keeps meetings approximately 1/3rd shorter while producing the same results (52)*

Effects of Custom Software: Custom software can seem like a simple and potentially cheaper solution than a ready-made alternative. However, after starting with a custom solution any further expansion or development also requires custom software. Professionally developed software suites were also identified as more likely to offer increased flexibility in order to support the business in the long–term. A discussion with management has also indicated that this would have been less expensive over the life-cycle period of Jasper. Additionally, there is often less risk in selecting a professional solution - as Chiptech discovered, losing the original developer requires a large time investment in order for new staff to understand the system sufficiently to alter it. In future I would recommend purchasing software if it is crucial to the business.

9.5 Closing Statement

The result was a successful base for a QMS, and an identified future goal for Chiptech despite the issues encountered during the project. Using these goals, a second project plan will be developed for submission to management and progress on this QMS will continue.

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1 Appendix A: Other Quality Management Systems Investigated

1.1 ISO 13485:2003

ISO 13485:2003 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory standards applicable to medical devices and related services. (33)

To be more specific, when comparing this standard to ISO 9001, ISO 13485 stresses the safety and efficacy of medical devices being produced. It includes risk management processes, adherence to regulatory standards, and is more prescriptive in insisting the development and use of formal procedures. In addition this standard allows the exclusion of certain aspects that are in conflict or not applicable with regulatory standards (see section 7 of standard). This is done by providing a risk-based approach for determining the level of rigor required when implementing the standard.

1.2 Baldrige Performance Excellence

The Malcolm Baldrige National Quality Award is a formal U.S. based award for recognition of both public and private sector "Performance Excellence". Named after Malcolm Baldrige, the U.S. Secretary of Commerce from 1981 to 1987, this award is given to promote awareness of performance excellence and to identify organisations to act as "role-models" within the United States.

The award itself serves a dual purpose:

- Identifying "role models" for other organisations and helping assist organisations with assessing their improvement efforts
- Diagnosing their overall performance management system.

The criteria are in seven groups, how each o sections interact is shown below:

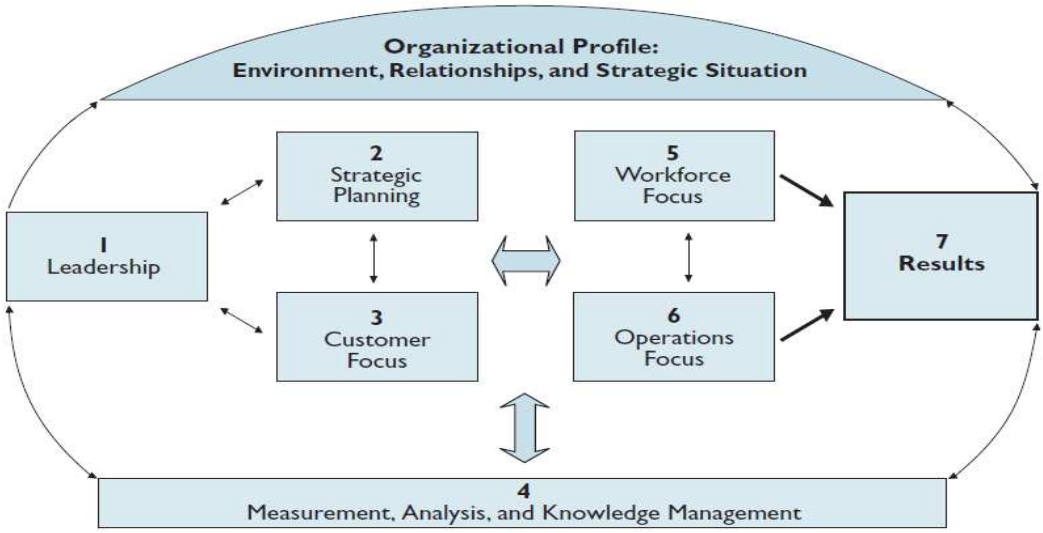

Figure 6: Baldrige Business Excellence overview (34)

Each section is broken down into further specifications (detail available on the organisations web site). The sections are used as criteria for providing proof of each stage. The exact implementation is not specified, only the outcomes and the presence of a definable system.

This places Business Excellence in a category outside of pure Quality Management, as it is neither a framework nor a standard. However it does provide the essence for future development, a self-critical process for grading a business to determine areas to strive for improvement. It should be noted as the next progression once the QMS is stabilised – it delivers a rather heuristic approach to developing an ideal business. The available marking schedule can be used as a guide or a benchmark once the base principles of Chiptech's QMS have been implemented and accepted.

1.3 Toyota Production System

The Toyota Production System is similar to TQM, and comprises both management practices and the philosophy behind each. TPS was the major precursor to Lean Manufacturing, which has become popular with manufacturers today.

The Toyota website dictates that TPS has three desired outcomes: (35)

- To provide the customer with the highest quality vehicles, at lowest possible cost, in a timely manner with the shortest possible lead times
- To provide members with work satisfaction, job security and fair treatment
- It gives the company flexibility to respond to the market, achieve profit through cost reduction activities and long-term prosperity

Literature for TPS indicates that its basis is formed around the following three ideals:

- Muri: Design out overburden
- Mura: Design out inconsistency
- Muda: Eliminate waste

Which were further developed into the base principles for "The Toyota Way" (19) (18):

- Continuous Improvement
    - Challenge (Forming long-term vision, and realising these)
    - Kaizen (Improving business operations, drive for innovation and evolution)
    - Genchi Genbutsu (Go to the source to find the facts, and make the correct decisions)
- Respect for People
    - Respect
    - Teamwork
- Think Long-term
- The Right process will produce the Right Results
- Add value to the organisation through your people, and partners
- Continuously solve the root problem, and this will drive organisational learning (worth noting that this is also Argyris' Double Loop Learning)

TPS is heavily based around Just-In-Time (JIT) or Lean manufacturing, which is the process for Muda (Eliminating waste). There are seven kinds of waste identified by TPS:

1. Over Production
2. Inventory
3. Motion
4. Waiting
5. Transportation
6. Overprocessing
7. Re-processing/Defects

Some literature includes an 8th waste:

8. Under-utilisation of staff

This discipline concentrates on ensuring that the business is operating efficiently, and can respond with a maximum amount of manufacturing agility.

In the longer term (i.e. once the QMS system has stabilised) it would be beneficial for Chiptech to consider venturing in to Lean Manufacturing, as this has been proven to deliver results in industry.

2 Appendix B: Document List

2.1 Document List and Overview

This section details all the documents currently created for the QMS. These documents are grouped as they exist in the Master Document List (below), with the creators of each document included in parenthesis.

Chiptech Master Document List (Carl)

This document contains a list of all QMS documents, their revisions, issue dates, review dates, required review periods, locations (both electronic and paper), and stakeholders (in terms of department) that require signing off on any change.

2.1.1 Quality Policy and Manuals

PD1001: Quality Policy (Executive committee)

This is the founding document, and contains an agreed-upon and signed off set of initial targets, scope, and identifies the desired outcomes. Quality targets include:

- No faulty or mislabelled parts propagating to production
- 90% sales forecasting accuracy
- 90% shipping accuracy
- No shortages in production due to lack of parts
- <2% warranty returns over the lifetime of the product
- Customer satisfaction surveys are required, and shall be actioned on
- No more than 10% feature creep on designs

This also includes the driving goals of increasing customer satisfaction, and actively improving Chiptech's processes and outputs through the process of continual improvement.

PD1002: Quality Manual (Carl, Paul)

This was developed in accordance with the ISO 9001 requirements, and outlines the entire quality management system under the following groups (only major groupings shown below):

- Scope and Purpose
- Chiptech Quality Management System Overview
- Management Responsibility
    - Commitment
    - Customer Focus
    - Planning
    - Responsibility, Authority and Communication
    - Management Responsibility to Staff
    - Management Review process
- Resource Management
- Product Realisation
    - Planning
    - Customer-related processes

    - Design and Development
    - Control of Purchasing
    - Production and Servicing
    - Control of Monitoring and Measurement Devices/Software
- Measurement, Analysis and Improvement
- Control of Non-conforming Product
- Analysis of all Data
- Continual Improvement, and Improvement Processes

This document provides the reasoning behind each, the goals and drivers, and finally the location of necessary documentation within the document control system.

PD1003: Control of Documents Procedure (Carl, Paul)
This document describes the processes for naming and filing documents, document creation procedures, and document control procedures.

PD1004: Internal Auditing (Carl)
Currently contains notes from literature around developing and reflecting on internal auditing. This document will be developed into a full internal audit process at a later date.

DO1001: Master Document Template (Carl)
Created in order to standardise the layout and formatting of all quality control documents. Also gives suggestions for sections and content.

DO1002: Future Goals (Carl)
This document is split into two sections, the first section consists of:

- On-going goals
- Goals for development

These sections are reviewed by the steering committee and updated quarterly. This defines the current goals for QMS development, and where Chiptech sees its QMS in the future.

The second section of the document is open for alterations at any time, and contains:

- Possible QMS improvements

These options are items for consideration during the steering committee meeting, and suggest possible avenues Chiptech may wish to develop.

2.1.2 Policies and Procedures

PD5001: Manufacturing QC, Training and Supervision (John, Paul)
Overview of desired outcomes, ownership and responsibilities for the following:

- Training of staff
- Supervision of staff members, and review, and communication procedures
- Quality Control policies for manufacturing, links to appropriate documents, and ownership with appropriate responses for QC failure

PD5002: Reel Changing Procedure (Carl)
This was identified as a single point of failure, and is important for meeting the quality policy goals. Included are the instructions for operation of the software used to control, confirm and track changes of part reels on the SMT machines. The process defines:

- Ownership
- User authorisation control (Administrative control)
- Uses
- Part acceptance checks
- Responses required for non-conforming parts

PD5003 – JUKI Program Creation Procedure (Carl)
This document was created as it was also identified as a single point of failure (and a very complex and involved procedure). This document indicates how to:

- Create CAD data from Altium or Protel
- The required manual alterations
- Loading of data into JUKI program creator via developed in-house software
- Creating new components within the JUKI program database
- Procedure for JUKI program verification
- Procedure for first prototype run, including common issues and required checklist

PD5004 – Non-conforming Product (Carl)
This contains flow charts for the process of dealing with non-conforming product, including both in-coming parts and product outputs.

Also includes the necessary procedures for checking parts on receipt - required to confirm incoming parts.

PD4001 – Purchasing Procedure (Carl)
This document dictates the necessary steps and authorisation required in order to purchase goods. These are separated into three distinct groups: First-time (or one-off) purchases, production equipment purchases, and production part purchases. All groups include the authorisation procedure for purchase. Other variations described are:

- For first or once-off purchases this includes the steps required to determine the payment method (credit card, TT or creation of an account), how to perform each of these steps, and what documentation or procedures are required to be completed or developed upon receipt of the goods.
- The production equipment process identifies required sign-off procedures and tests that need to be identified, documented, and performed on the receipt of goods.
- The production parts procedure identifies the requirements for batch testing, checks to confirm parts are not counterfeit, and sign-off documentation required on receipt of parts.

2.1.3 Forms

FM5001: Manufacturing Supervision Form (Carl, Paul)

This is a production document containing the documentation required to be completed by production for the supervision process in accordance with processes identified in the quality manual.

DO3001: Component Change (Carl)
This document is a word template that contains the procedure and layout for a component change investigation. This includes necessary sign-off procedures, and is to be used by engineering when a component is obsoleted, or a component change notice is received from a manufacturer.

DO3002: Product Release Sign-off (Carl, Paul)
This template contains the procedure and layout for signing off the release of a product change, or a sample of product to a new customer.

2.1.4 General Documents

The documents in this section are usually guides as opposed to processes – they contain the general outline and some detail, but not to the point of identifying every single aspect in detail.

DO3000: Selecting the Appropriate Project Template (Carl)
Given the differing levels of project complexity, sometimes a full plan is required whereas other times the solution is obvious given a simple project. The diagram is included below to indicate how flow-diagrams have been developed within this project – the aim was to ensure the "kiss" principle, and have the detailed description later in the document. This allows for these diagrams to be separated and referenced easily.

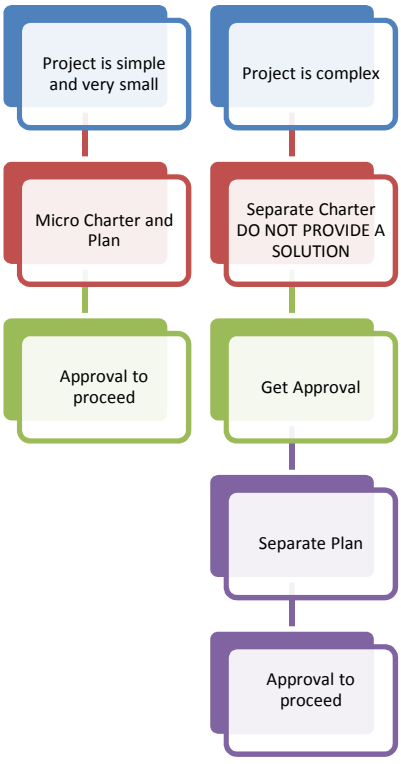

Figure 7: Simple template selection guide given as example

This layout also allows for more project frameworks targeted at differing project magnitudes to be created at a later date.

DO3001: Project Charter (Carl, Paul)

Updated and expanded from a previous version. The document contains the necessary considerations when bringing a project to management for review. This includes the distinction to NOT solution jump (identified as vital), and has a new section dedicated to risk identification.

DO3002: Project Plan (Carl, Paul)
This document is for complex or large projects where a separate charter has already passed the approval stagegate. This template requires the developer to consider the following:

- Scope
- Resources and Constraints
- Applicable Standards
- Further Risk Analysis
- Stakeholders
- Milestones, and Deliverable Schedules
- Feature Matrix
- Work Breakdown Structure

This may be developed partially in conjunction with the project specifications, and will need to be approved prior to the project starting.

Also any later changes to the plan must be signed off by the stakeholders identified during the development of this document.

DO3003: Project Micro Charter and Plan (Carl, Paul)
A joint charter and project plan template, used for those cases where there is a need to launch a separate project, but the details of this (and solution) are deemed obvious by engineering. This proposal is still delivered to management for consideration, so if it is deemed necessary this can be split into a separate charter and plan later.

The goal of this document is to streamline the project creation process, so that projects and project records do not become a large monolithic dump of information.

DO3004: Tools for Development (Carl)
Still in development – this contains tools for quality consideration and risk analysis, and is expected to grow with any new tool discovered that might be applicable. It has been identified that the inclusions of “ISO 30001: Risk management” would be beneficial in the future. This currently contains:

- Ishikawa diagram (cause and effect analysis)
- FMECA
- Statistical Process Control
- (Custom) Guide to Deciding What to Measure

This is to be used as a knowledge base and reference for enabling better analysis, and includes consideration for how the end result will be maintained and monitored.

DO6001: Product Realisation Guide (Carl)
This guide contains the process that Chiptech shall follow in order to develop a product from idea into reality. This includes:

- Identifying the stages through the entire development cycle
- Guides to give an indication on what each stage requires or may require
- Appropriate tools for use in each stage
    - Porter's five forces
    - PESTLE
    - Cause and effect diagram
    - Failure mode effect and criticality analysis
- Market analysis requirements
- Business case development
- Development of a specification through communication with stakeholders
- Research and development requirements
- Rough estimates on time-scales (from previous projects) as an indication of overall stage lengths
- Requirements for prototyping and release to production

The aim of this document was to ensure that the bare minimum of stages are identified, and include supporting processes and ideas that may be leveraged for use in the development cycle.

DO5001: Jasper Overview and Guide (Carl)

Identified as a topic containing multiple single points of failure, and extremely crucial to business continuity. This document gives an overview of every single feature and module that exists within the production system 'Jasper'. This includes, but is not limited to: (Note, cannot include all due to document size limitations)

- Installation of software
- Creating a new 'Project' within the system
- Forecasting ability and use
- Adding new parts
- Stocktaking process
- How every single form functions for processing, un-processing, re-processing, tracking in-house repairs, tracking servicing, product history, and other functions required for production
- How each report is generated, and what data is available/how to obtain this data
- Servicing procedure (in-house and sold to customer)
- SMT functionality for integrating with machinery
- Parts ordering process
- Placing customer orders
- Completing customer orders
- Allocating and controlling CSIDs (these are supplied by customer for tracking alarms)

DO7001: VPN Instructions (Carl)

As the Virtual Private Network functionality was developed recently by myself (single point of failure), this document exists for how to control access, allocate passwords and keys, revoke keys, and instructions for use.

2.1.5 Quality Control documents

QC5001: Pearl Std QC Inspection Form (Jim)

Due to the complexity of Pearl this contains specific procedures for the Pearl product. This includes the QC process staff are required to be trained in, the printer-friendly form for documentation purposes, and the process to occur when a QC failure is detected.

QC5002: ERICA QC Inspection Form (Carl, Paul)

Same as prior document, for ERICA product.

QC5003 Pearl Std QC Inspection Follow-Up Form (Jim)

Specific follow-up form required for Pearl, due to its complexity.

QC5004: QC Failure Follow-Up Form (Carl, Paul)

General follow-up form for the QC investigator to complete in order to confirm that the failure has been corrected in the long-term, includes processes and time-span for this procedure.

QC5005: Fault Analysis Procedure Form (Carl)

This document is a generic fault analysis form. This includes the OPDCA framework, risk analysis guide, check-list for follow-up procedure, and sign-off requirements.

This form is used for investigating faults for anything not identified by a specific QC procedure, and is useful both as a record and as a means of communicating the process and progress of the investigation to others.

2.1.6 Work Instructions

The following documents were written to: train new production staff, to be used as a reference document to ensure repeatability of processes, and tighten variation in outputs. All of these documents cover significant detail in a step-by-step basis, and are written so that an untrained staff member can follow these and achieve the desired result.

(Content description omitted as titles make these self-evident)

WI5001: ERICA Work Instructions (Carl, John)

WI5002: SERMOD Cable Work Instructions (Paul)

WI5003: Pearl Advanced Work Instructions (Jim)

WI5004: Pearl Work Instruction (Jim)

I am also currently in the process of completing work instructions for other (lower priority) product, including:

- PRU 51 and PRU 52
- Felix
- ULDD
- Standard Transmitter
- ERIC Servicing
- PRU Servicing

These documents are still in the first draft stages, and are not yet assigned within the QMS.

3 Appendix C: Initial Metric Results

Below are examples to add value to this report (Axis omitted for confidentiality).

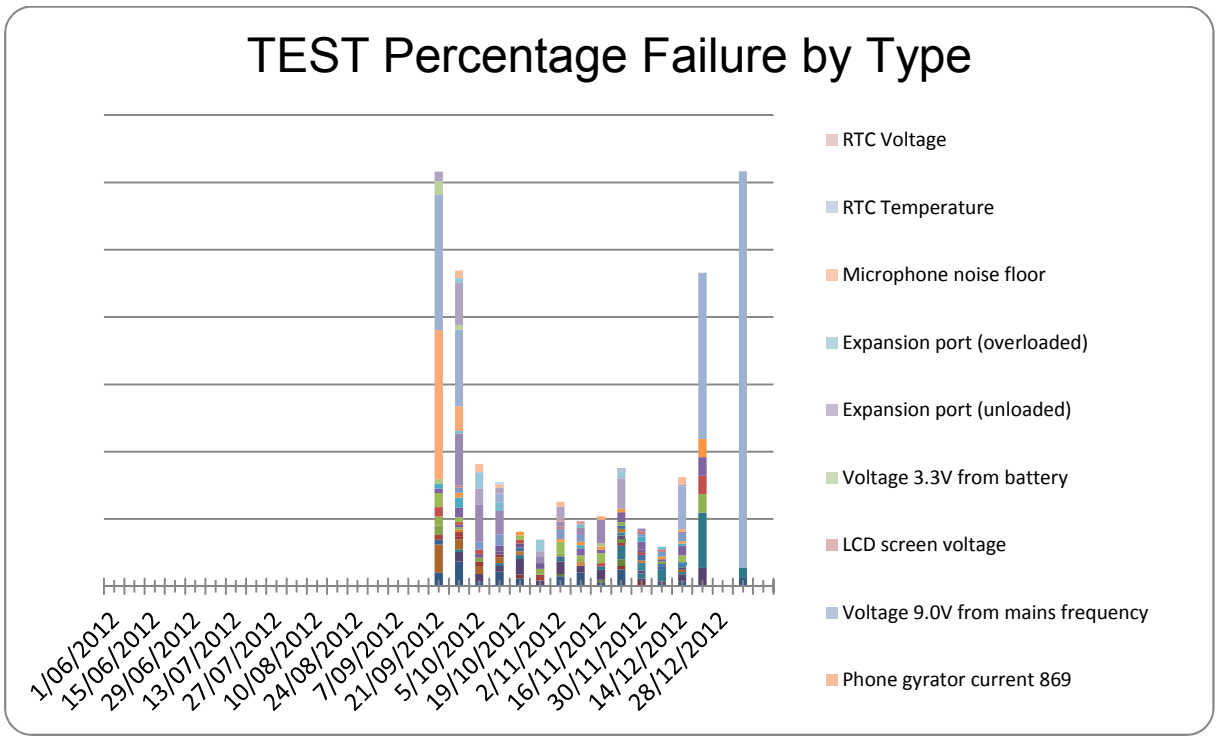

Figure 8: Percentage ERICA TH/TEST Failures Example - Axis omitted

We can observe the test-jig initially being set up in the September period above, and then the recent quality failures (light blue) dominating from the 14th of December onwards – these were first detected using this tool. Ideal failure rate here is around 10%, as we do use this stage to reject some components that are outside our desirable specifications (but are within manufacturer tolerance).

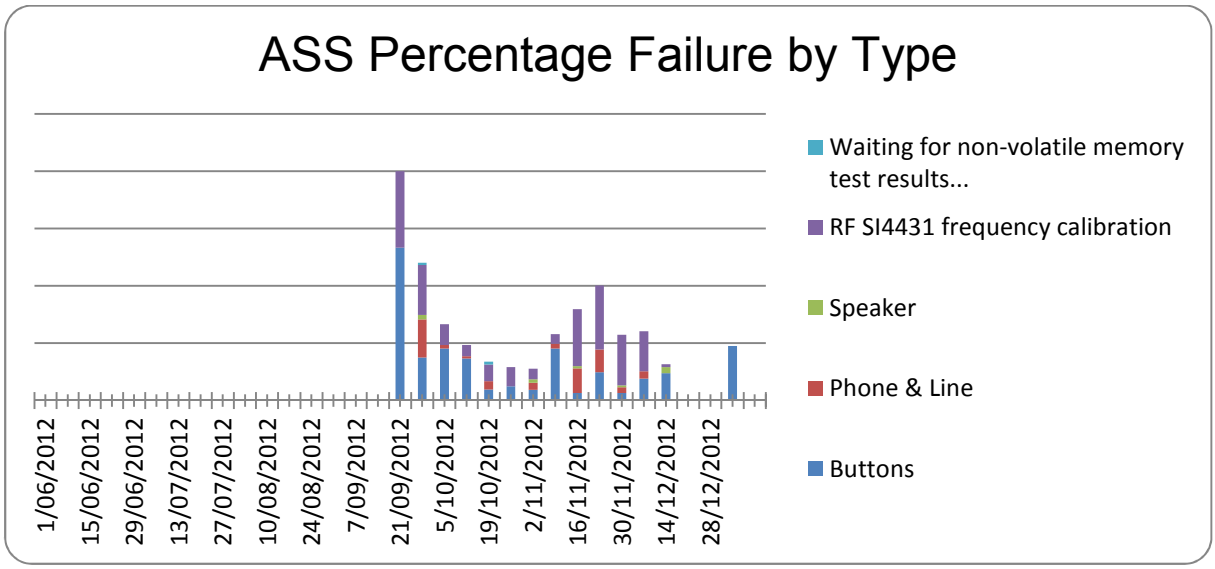

Figure 9: Percentage ERICA Assembly Failures Example - Axis omitted

The graph above shows a desirable trend in test results, and the purple bars dominating above have been corrected (a type I failure).

4 Appendix D: Tools Introduced

4.1 Cause and effect analysis / Fishbone / Ishikawa Diagram

This simple diagram was created by Kaoru Ishikawa and can be used for the following purposes

- Discovering root causes to problems
- Determining bottlenecks in processes
- Brainstorm failure cases
- **RISK/Failure mode determination**

The steps to creating an Ishikawa (Fishbone) diagram like the one below are as follows:

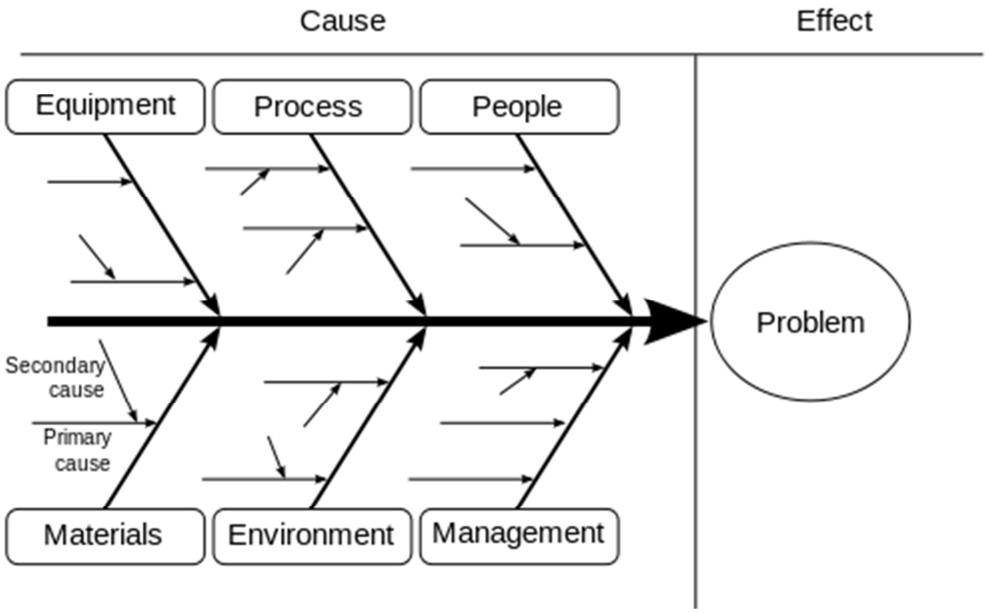

Figure 10: Ishikawa (Fish-bone) diagram example (36)

1. Identify the problem and draw it as a box on the right-hand side
2. Work out the major issues/factors that may be part of the problem, drawing these as spines coming out of the diagram
3. For each of these factors consider factors that may be related to these issues. You can proceed to repeat this process for the factors you just determined also
4. Finally, looking at the diagram and observe densities, likelihoods, and common themes
    a. This is the step that deciphers meaning from the chaos of ideas.

It is also possible (and beneficial) to do this using a whiteboard and sticky notes, brainstorming the ideas and then laying them out in an orderly fashion.

4.2 Plan-Do-Check-Act

The Plan-Do-Check-Act is a simple four-step iterative method for managing the improvement of processes. It describes a very basic framework for approaching continuous improvement steps, and quite simply just ensures that the solution is implemented correctly, and achieves what is desired.

With regards to TPS (Toyota Production System) and lean thinking, there is an additional step placed at the start "Observe" – this is to ensure that the correct issue is being solved, following their principle of "GenchiGenbutsu" (37) (38) – Going to the source to find the facts, and make the correct decisions.

Additionally, the PDCA framework is at the heart of the developing agile project management methodology, which has recently been gaining popularity over the last decade (39), so despite its apparent simplicity it appears to be a most-valued tool.

Figure 11: OPDCA diagram created for quality toolset

4.3 Deciding What to Measure

Author John Oakland indicates that it is important when considering metrics to ensure you are measuring progress in five main areas (40):

- Effectiveness
- Efficiency
- Productivity
- Quality
- Impact

It is important to consider how to address and measure each of these success factors, or at least explicitly exclude those that are irrelevant.

Measurements are inherently a tool for ensuring or determining success. There are common characteristics that are desirable for selecting measurements, such as:

- Completeness – anything unmeasured can potentially suffer from neglect
- Relevance and validity – A change or variance in your measurement should correlate to the need for action, and not suffer from noise.
- Ease of measurement – measurements need to be able to be obtained simply and with minimal additional cost.
- Ease of understanding – It must be obvious/intuitive what the measurements are actually representative of, so that everyone can understand them.

These measurements can be applied to measuring product quality, management quality, or even project success.

4.4 Statistical Process Control (SPC)

SPC requires knowledge of what the process is, what the inputs / outputs are, and how the stakeholders and their requirements are defined.

A process that is monitored and measured can be controlled by gathering and using the appropriate data. SPC defines a framework for applying and analysing the extent, variability, and repeatability of a process.

This is achieved by answering the following questions:

- Are we capable of doing the job correctly?
- Do we continue to do the job correctly?
- Have we done the job correctly?
- Could we do the job more consistently and set targets?

This provides knowledge of process capability.SPC techniques also have value in non-manufacturing areas, such as marketing and sales, purchasing, invoicing, finance, distribution, training and personnel.

4.5 Failure Mode Effects and Criticality Analysis

(Note, this is taken from the 2012 Master of Engineering Management booklet "A Case-based Engineers' Guide to Error Proofing & Fault Detection in Complex Systems")

FMEA is a methodology designed to identify possible failures in a system, and is used as a form of design review – whether this be the design of a manufacturing process, product, service, or otherwise. "Failure modes" describe the way the failure occurs and "effects analysis" studies the consequences of those failures (41) (42).

FMEA can be used when designing/redesigning a new/existing process, product or service; and can be applied periodically throughout the life of the process, and also when failure occurs (42).

The steps for performing a failure mode and effects analysis (43)include:

- Assemble the team and establish the ground rules
- Gather and review relevant information
- Identify the item(s) or process(es) to be analysed
- Identify the function(s), failure(s), effect(s), cause(s) and control(s) for each item or process to be analysed
- Evaluate the risk associated with the issues identified by the analysis
- Prioritise and assign corrective actions
- Perform corrective actions and re-evaluate risk
- Distribute, review and update the analysis, as appropriate

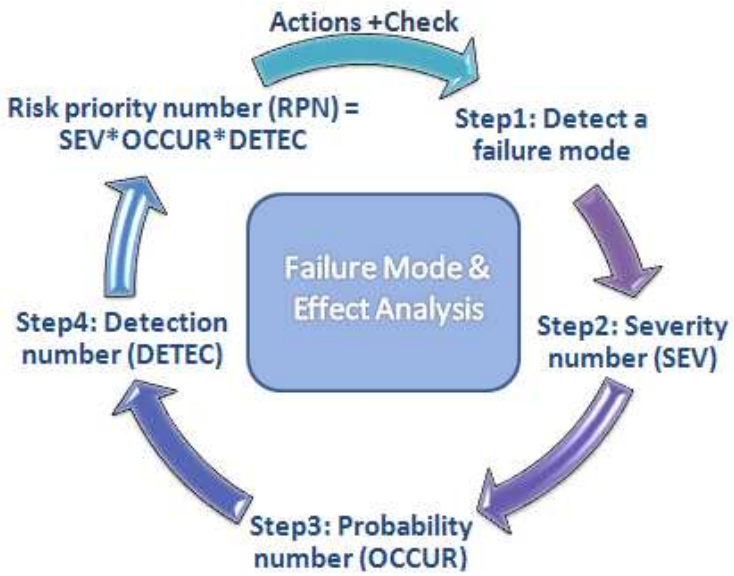

Figure 12: Four Step FMEA Cycle

A simple illustration of the FMEA cycle can be seen in Figure. 3-3 (41).The cycle shown incorporates the Risk Priority Number (RPN) method used to evaluate the risk associated with the potential problems identified through the analysis. RPN is a quantitative risk assessment method which can be used to compare issues within the analysis and to prioritise problems for corrective action. This

method requires the severity of the effect of the failure to be rated, and the probability of occurrence and detection for each cause of the failure (43).

'Criticality analysis' is an extension of the FMEA method and is commonly known as failure mode effects and criticality analysis (FMECA). The quantitative and qualitative forms of FMECA are described by theMIL-STD-1629A standard.

4.6 PESTLE Analysis – The Market

The PESTLE analysis is a simple tool that ensures that the necessary topics are considered, it is in itself an acronym for:

Political
Investigate any "political" barriers, these can include government action, or just issues surrounding the adoption or sales due to previous issues in the market, or politics within an organisation (i.e. contractual obligations of others)

Economic
This consideration has some effect but is likely not the weightiest of aspects, this includes:

- Looking at currency rates – is our product going to become more expensive to overseas markets in the future?
- Is there going to be some funding cuts or increases in the future? What is the trending history of such?
- Industry spending trends?
- Price elasticity – is demand for the product affected significantly by income, or is consumption fairly regular.

Social
This section covers more of the "soft" side of the market, product acceptance by customer chain, product preferences (see Apple's success for this), etc. Basically this section covers market analysis of the product from a customer's point of view, and should consider the entire customer chain.

Technical
What level of technical advancement is there in this area, and at what speed is this progressing? Also are there any trends for new technology outside of this market that could be leveraged to develop more desirable products (GPS and GSM/WCDMA are examples – technologies unrelated but that have impact on what we design).

Legal
This involves a quick check into the legal aspects of producing the desired product – look for required standards, and some products require businesses to have specific accreditations (i.e. ISO 13485 – Medical Equipment Manufacturer).

Consult with the Engineering department on this one, as some standards are very expensive to obtain, and may be outside our skill set (and we would need to find a third-party to do this for us).

Environmental

This section is relatively “new” in consideration when designing – basically there are two aspects:

- Do we want to market this or ourselves as “green” technology
- Are there any regulations/laws governing what material we use and disposal methods we must make available.

RoHS is an obvious example.

4.7 Porter’s Five Forces – Market Strategy

This tool is useful for determining the driving factors in a market space. Having used this a few times, my personal experience is that the benefits of this lie in brainstorming potential issues, ensuring that factors are not neglected when one “cannot see the forest for the trees”.

In essence

- Use the five factors given in the diagram to brainstorm positive factors, negative factors and potential issues.
- Then brainstorm how to target the positives, and mitigate the negatives/issues.

Leverage off of others ideas and thoughts to make sure we know how we want to progress, and what to do if an issue makes itself apparent.

Figure 13: Porter's Five Forces diagram for product realisation guide